INTERNATIONAL STANDARD

ISO 80601-2-72

Second edition
2023-06

Medical electrical equipment —

Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients

Appareils électromédicaux —

Partie 2-72: Exigences particulières pour la sécurité de base et les performances essentielles des ventilateurs utilisés dans l'environnement des soins à domicile pour les patients ventilo-dépendants

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives or www.iec.ch/members_experts/refdocs).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see https://patents.iec.ch).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electric equipment,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-72:2015), which has been technically revised.

The main changes are as follows:

— added requirements for display during calibration of gas monitors;

— clarified *maximum limited pressure* requirements;

— clarified high *airway pressure alarm condition* requirements;

— added requirements for *ventilator system recovery*;

— added requirements for response to an increase in set oxygen (O_2) concentration; and

— harmonization with ISO 20417, where appropriate.

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

Introduction

This document specifies requirements for *lung ventilators* that are intended for use in the *home healthcare environment* for *patients* who are dependent on *ventilation* for their life support. These *ventilators* are frequently used in locations where the *supply mains* driving the *ventilator* is not reliable. These *ventilators* are often supervised by non-healthcare personnel (*lay operators*) with varying levels of training. *Lung ventilators* conforming with this standard can be used elsewhere (i.e. in healthcare facilities).

In referring to the structure of this document,

— “clause” means one of the 5 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes 201.7, 201.8, etc.); and

— “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

Annex C contains a guide to the *marking* and labelling requirements in this document.

Annex D contains a summary of the *symbols* referenced in this document.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

Medical electrical equipment —

Part 2-72:
Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients

201.1 Scope, object, and related standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

201.1.1 Scope

Replacement:

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

This document applies to the *basic safety* and *essential performance* of a *ventilator* in combination with its *accessories*, hereafter referred to as *ME equipment:*

— intended for use in the *home healthcare environment;*

NOTE 2 In the *home healthcare environment*, the *supply mains* driving the *ventilator* is often not reliable.

NOTE 3 Such *ventilators* can also be used in non-critical care applications of *professional healthcare facilities.*

— intended for use by a *lay operator*; and

— intended for those *patients* who need differing levels of support from *artificial ventilation* including for *ventilator-dependent patients*.

A *ventilator* is not considered to use a *physiologic closed-loop control system* unless it uses a physiological *patient* variable to adjust the *ventilation* therapy settings.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to a *ventilator breathing system* or to a *ventilator* where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilator*.

EXAMPLE Breathing tubes, *connectors*, water traps, expiratory valve, *humidifier*, *breathing system filter*, external electrical power source, and *distributed alarm system.*

NOTE 4 If a clause or subclause is specifically intended to be applicable to *ME equipment* only or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except for the requirements specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 5 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document does not specify the requirements for:

— *ventilators* or *accessories* intended for critical care applications, which are given in ISO 80601-2-12;

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13;

— *ventilators* or *accessories* intended for emergency and transport which are given in ISO 80601-2-84;

— *ventilators* or *accessories* intended for homecare ventilatory support equipment (intended only to augment the *ventilation* of spontaneously breathing *patients*), which are given in ISO 80601-2-79 and ISO 80601-2-80;

— obstructive sleep apnoea therapy *ME equipment,* which are given in ISO 80601-2-70;

— high-frequency *ventilators*, which are given in ISO 80601-2-87.

— respiratory high-flow therapy equipment, which are given in ISO 80601-2-90;

NOTE 6 An ISO 80601-2-72 *ventilator* can incorporate high-flow therapy operational mode, but such a mode is only for spontaneously breathing *patients*.

— user-powered resuscitators, which are given in ISO 10651-4;

— gas-powered emergency resuscitators, which are given in ISO 10651-5;

— oxygen therapy constant flow *ME equipment*; and

— cuirass and “iron-lung” *ventilators.*

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for a *ventilator,* as defined in 201.3.217, and its *accessories*.

Accessories are included because the combination of the *ventilator* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of a *ventilator*.

NOTE 1 This document has been prepared to address the relevant *essential principles*[31] and labelling[32] guidance of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

NOTE 2 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex DD.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[33] as indicated in Annex EE.

201.1.3 Collateral standards

Amendment (add after existing text):

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and in 201.2 of this document.

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2016+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206, 208 and 211 respectively. IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-12 do not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards can modify, replace, or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular *ME equipment* under consideration, and may add other *basic safety* or *essential performance* requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard document number (e.g. 202.4 addresses the content of IEC 60601-1-2, Clause 4 collateral standard, 208.4 addresses the content of IEC 60601-1-8, Clause 4 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

— "Replacement" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard is replaced completely by the text of this document.

— "Addition" means that the text of this particular standard is additional to the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard.

— "Amendment" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard is amended as indicated by the text of this document.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to IEC 60601-1:2005+AMD1:2012+AMD2:2020, any applicable collateral standards, and this document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5359:2014+AMD1:2017, *Low-pressure hose assemblies for use with medical gases*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the* medical *device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO 80601-2-74:2021, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62304:2006+AMD1:2015, *Medical device software - Software life cycle processes*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

IEC 81001-5-1:2021, *Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle*

IEC Guide 115:2021, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

201.3.201
accompanying information
information accompanying or *marked* on a medical device or *accessory* for the user or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the medical device or *accessory*, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the medical device or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the label, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g. CD/DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2021, 3.2, modified — deleted note 4.]

201.3.202
acknowledged
state of an *alarm system* initiated by *operator* action, where the auditory *alarm signal* associated with a currently active *alarm condition* is inactivated until the *alarm condition* no longer exists or until a predetermined time interval has elapsed

Note 1 to entry: *Acknowledged* only affects *alarm signals* that are active at the time of the *operator* action.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.37]

201.3.203
airway device
device intended to provide a *gas pathway* to and from the *patient's* airway

[SOURCE: ISO 4135:2022, 3.8.1.2]

201.3.204
airway pressure
***P*aw**
pressure at the *patient-connection port* or at the distal *outlet* of the equipment where there is no *patient-connection port*

Note 1 to entry: The *airway pressure* can be derived from pressure measurements made anywhere within the equipment.

[SOURCE: ISO 4135:2022, 3.1.4.41.1]

201.3.205
alarm condition delay
time from the occurrence of a triggering event either in the *patient*, for *physiological alarm conditions*, or in the equipment, for *technical alarm conditions*, to when the *alarm system* determines that an *alarm condition* exists

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.2]

201.3.206
alarm limit
threshold used by an *alarm system* to determine an *alarm condition*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.3]

201.3.207
alarm off
state of indefinite duration in which an *alarm system* or part of an *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.4]

201.3.208
alarm paused
state of limited duration in which the *alarm system* or part of the *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.5]

201.3.209
alarm setting
alarm system configuration, including but not limited to:
– *alarm limits*;
– the characteristics of any *alarm signal* inactivation states; and
– the values of variables or parameters that determine the function of the *alarm system*

Note 1 to entry: Some algorithmically-determined *alarm settings* can require time to be determined or re-determined.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.8]

201.3.210
alarm signal generation delay
time from the onset of an *alarm condition* to the generation of its *alarm signal(s)*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.10]

201.3.211
artificial ventilation
intermittent elevation of the pressure in the *patient's airway* relative to that in the *lungs* by external means with the intention of augmenting, or totally controlling, the *ventilation* of a *patient*

EXAMPLE Means used to provide *artificial ventilation* are manual resuscitation; mouth-to-mouth resuscitation; automatic *ventilation*; mechanical *ventilation*.

Note 1 to entry: Common classifications of areas of application of *artificial ventilation* are: emergency; transport; home-care; anaesthesia; critical care; rehabilitation.

Note 2 to entry: Classifications used to denote means used for *artificial ventilation* include: positive-pressure; negative-pressure; gas-powered; *operator*-powered; electrically-powered.

Note 3 to entry: Negative-pressure *ventilation* elevates the relative pressure in the airway by intermittently lowering the pressure in the *lungs*.

[SOURCE: ISO 19223:2019, 3.1.10]

201.3.212
attack
attempt to destroy, expose, alter, disable, steal or gain unauthorized access to or make unauthorized use of an asset

[SOURCE: IEC 81001-5-1:2021, 3.5]

201.3.213
audio off
state of indefinite duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.12]

201.3.214
audio paused
state of limited duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.13]

201.3.215
BAP
quantity by which the baseline *airway pressure* is set to be positively offset from the ambient pressure

[SOURCE: ISO 19223:2019, 3.10.2, modified — deleted notes.]

201.3.216
bias flow
flow that passes through the *ventilator breathing system* to the *exhaust port* but is not intended to contribute to the work of *lung* ventilation

[SOURCE: ISO 19223:2019, 3.7.7, modified — deleted notes.]

201.3.217
biocompatibility
ability to be in contact with a living system without producing an unacceptable adverse effect

Note 1 to entry: Medical devices may produce some level of adverse effect, but that level may be determined to be acceptable when considering the benefits provided by the medical device.

[SOURCE: ISO 18562-1:2017, 3.2]

201.3.218
body temperature and pressure saturated
BTPS
ambient atmospheric pressure, at a temperature of 37 °C, and at a relative humidity of 100 %

[SOURCE: ISO 4135:2022, 3.1.1.7]

201.3.219
breathing system
pathways through which gas flows to or from the *patient* at respiratory pressures and continuously or intermittently in fluid communication with the *patient's* respiratory tract during any form of *artificial ventilation* or respiratory therapy

[SOURCE: ISO 4135:2022, 3.6.1.1, modified — deleted notes.]

201.3.220
breathing system filter
BSF
device intended to reduce transmission of particulates, including microorganisms, in *breathing systems*

[SOURCE: ISO 23328-2:2002, 3.1]

201.3.221
cleaning
removal of contaminants to the extent necessary for further *processing* or for *intended use*

Note 1 to entry: *Cleaning* consists of the removal of adherent soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated *process* that prepares the items for safe handling or further *processing*.

[SOURCE: ISO 17664-2:2021, 3.1, modified — replaced 'and/or' with 'or'.]

201.3.222
connector
fitting to join two or more components

EXAMPLE *Connectors* for *low-pressure hose assembly* are any of a range of mating components intended to maintain gas specificity by the allocation of a set of different diameters to the mating *connectors* for each particular gas.

[SOURCE: ISO 4135:2022, 3.1.4.5]

201.3.223
continuous flow
gas flowing continuously through the *ventilator breathing system*, with a proportion intermittently passing to the *patient's lung* whenever the *airway pressure* is raised by the *ventilator* or an *operator* action, or flow is demanded by a *patient's* inspiratory effort

[SOURCE: ISO 19223:2019, 3.7.8, modified — deleted notes.]

201.3.224
CPAP
continuous positive airway pressure
ventilation-mode or sleep-apnoea breathing-therapy mode in which the *patient* breathes continuously at a set *airway-pressure* level, above ambient pressure

Note 1 to entry: *CPAP* is intended to maintain the *airway pressure* at its *set* value apart from the inevitable minor deviations that are necessary for it to perform its function. Although there are currently no tests for acceptable levels for such deviations, they are expected to neither add to nor subtract from the *patient's* perceived work of breathing to a greater extent than could be experienced during natural breathing.

Note 2 to entry: This definition excludes the use of the term to describe *ventilation-modes* where spontaneous inspirations are supported by intermittently elevated pressures other than with the intention to compensate for any actual or perceived imposed work of breathing.

Note 3 to entry: Because, as used for this *ventilation-mode*, the concept of a *CPAP* level coincides with that of a baseline *airway pressure* the setting could be designated as for either concept but as the intention of the *operator* selecting this *ventilation-mode* will be to achieve a specific *CPAP* level, this becomes an acceptable admitted term to designate the set quantity.

Note 4 to entry: Although at the periphery of the spectrum of what constitutes a *ventilation-mode*, *CPAP* is included in this document because it is commonly made available on typical critical care *ventilators* for use as part of a continuum of a *patient's* treatment without the necessity to change to another device.

Note 5 to entry: It is possible for a *ventilation-mode* resembling *CPAP* to be realized on a *ventilator* by the use of CSV (continuous spontaneous *ventilation*) with the pressure-support (PS) *set* to 'zero' or 'none' but CSV set in this way is not equivalent to *CPAP* if its performance in response to a spontaneous inspiration is dependent on the setting of an appropriate trigger level.

Note 6 to entry: On *ventilator*s equipped with ACAP, this adjunct will enable unrestricted breathing whenever *CPAP* is selected.

Note 7 to entry: *CPAP* is a Group 4b *ventilation-mode*. Because no *inflation-type* is selected this *ventilation-mode* is identical to its ventilation-pattern and there is no necessity to distinguish between them. The systematic *ventilation-mode* name becomes, therefore, simply, *CPAP*. On *ventilator*s where *CPAP* is enabled by means of an ACAP adjunct the systematic code is CPAP <ACAP>.

Note 8 to entry: When used for sleep-apnoea *breathing*-therapy, *CPAP* is not classed as a *ventilation-mode* – it becomes a sleep-apnoea *breathing-therapy mode*. Although the principle clinical intention of such a therapy mode is to maintain a positive pressure in the *patient's* airway during sleep in order prevent airway obstruction by the soft tissues in the throat it has become a common practice to reduce this pressure during expiration, principally to improve *patient* acceptability. *Ventilation-modes* with this feature are typically identified with names that allude to this use of two levels of positive *airway pressure*. The generic name adopted for the designation of such a breathing-therapy mode in this document is bi-level PAP.

[SOURCE: ISO 19223:2019, 3.11.15, modified — deleted note 9.]

201.3.225
cybersecurity
state where information and systems are protected from unauthorized activities, such as access, use, disclosure, disruption, modification, or destruction to a degree that the related *risks* to violation of confidentiality, integrity, and availability are maintained at an acceptable level throughout the life cycle

[SOURCE: IEC 81001-5-1:2021, 3.30]

201.3.226
Δ inspiratory pressure
differential *airway pressure* relative to baseline *airway pressure* during an *inflation phase*

[SOURCE: ISO 19223:2019, 3.6.7, modified — deleted notes.]

201.3.227
disinfection
process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 17664-1:2021, 3.3]

201.3.228
distributed alarm system
DAS
alarm system that involves more than one item of equipment of a *ME system* intended for delivery of *alarm conditions* with technical confirmation

Note 1 to entry: The parts of a *distributed alarm system* can be widely separated in distance.

Note 2 to entry: A *distributed alarm system* is intended to notify *operators* of the existence of an *alarm condition*.

Note 3 to entry: For the purposes of this document, technical confirmation means that each element of a *distributed alarm system* confirms or guarantees the successful delivery of the *alarm condition* to the next element or appropriate *technical alarm conditions* are created as described in IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.11.2.2.1.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.17]

201.3.229
end-expiratory flow
expiratory flow at the point of initiation of an *inflation* or an inspiration

[SOURCE: ISO 19223:2019, 3.7.6, modified — deleted notes.]

201.3.230
essential function
function or capability that is required to maintain *basic safety*, *essential performance*, a minimum of clinical functionality as specified by the manufacturer, and operational availability for the *medical device*

Note 1 to entry: *Essential functions* include, but are not limited to, the *safety* instrumented function (*basic safety* and *essential performance*), the control function and the availability of urgently needed functions and such allowing the *operator* to view and manipulate the *medical device* safely with the most urgently needed performance (operational availability). The loss of *essential function* is commonly termed loss of protection, loss of control and loss of view respectively.

Note 2 to entry: The term is derived from IEC 62443-4-2:2019, 3.1.20, and has been refined for the purpose and scope of this document.

[SOURCE: IEC/TR 60601-4-5:2021, 3.10]

201.3.231
essential principles
essential principles of safety and performance
fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

[SOURCE: ISO 16142-1:2016, 3.3]

201.3.232
exhaust port
port of the medical equipment or device from which gas is discharged to the atmosphere during *normal use*, either directly or via an anaesthetic gas scavenging system

[SOURCE: ISO 19223:2019, 3.14.2]

201.3.233
expiratory phase
interval from the start of expiratory flow to the start of inspiratory flow within a *respiratory cycle*

[SOURCE: ISO 19223:2019, 3.4.2, modified — deleted notes.]

201.3.234
false positive alarm condition
presence of an *alarm condition* when no valid triggering event has occurred in the *patient*, the equipment or the *alarm system*

Note 1 to entry: A *false positive alarm condition* can be caused by spurious information produced by the *patient*, the *patient*-equipment interface, other equipment or the *alarm system* itself.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.21]

201.3.235
firecall
method established to provide emergency access to a secure medical device

Note 1 to entry: In an emergency situation, unprivileged users can gain access to key systems to correct the problem. When a *firecall* is used, there is usually a review *process* to ensure that the access was used properly to correct a problem. These methods generally either provide a one-time use user identifier (ID) or one-time password or other suitable measures.

Note 2 to entry: Also referred to as "break glass" feature.

[SOURCE: IEC/TR 60601-4-5:2021, 3.11]

201.3.236
flow-direction-sensitive component
component or *accessory* through which gas flow has to be in one direction only for proper functioning or *patient* safety

[SOURCE: ISO 4135:2022, 3.1.4.15]

201.3.237
fresh gas
respirable gas delivered to a *ventilator breathing system*

[SOURCE: ISO 4135:2022, 3.1.1.16, modified — Added '*ventilator*' and deleted notes.]

201.3.238
gas intake port
port through which gas is drawn for use by the *patient*

Note 1 to entry: Gas is drawn at a sub-ambient pressure at a *gas intake port*, in opposition to an *inlet*, at which gas is provided by a medical gas supply system.

[SOURCE: ISO 4135:2022, 3.1.4.21 modified — replaced "apposition" with "opposition".]

201.3.239
gas output port
port of the *ventilator* through which gas is delivered at respiratory pressures to an *operator*-detachable part of the *ventilator breathing system*

[SOURCE: ISO 19223:2019, 3.14.3]

201.3.240
gas pathway
interior surfaces, over which gases or liquids that can be inspired, in a medical device bounded by the ports through which gases or liquids enter and leave the medical device including the *patient* interface or the interior surfaces of *enclosures* that are in contact with gases or liquids that can be inspired

Note 1 to entry: *Patient* contact surfaces such as the outer surfaces of a tracheal tube or the cushion of a *mask* are evaluated according to the ISO 10993 series.

EXAMPLE 1 The *ventilator breathing system*, *inlet* filter, gas mixer, blower and internal piping.

EXAMPLE 2 Enclosed chamber of an incubator including the mattress or the inner surface of an oxygen hood.

EXAMPLE 3 The inner surfaces of breathing tubes, tracheal tubes or *masks* and mouthpieces.

[SOURCE: ISO 18562-1:2017, 3.5]

201.3.241
gas return port
port of the *ventilator* through which gas is returned at respiratory pressures through an *operator*-detachable part of the *ventilator breathing system*, from the *patient-connection port*

[SOURCE: ISO 19223:2019, 3.14.4]

201.3.242
healthcare professional
appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services to families or communities

Note 1 to entry: This term functions as an adjective.

201.3.243
heat and moisture exchanger
HME
device intended to retain a portion of the *patient's* expired moisture and heat, and return it to the respiratory tract during inspiration

[SOURCE: ISO 9360-1:2000, 3.1]

201.3.244
high-pressure inlet
inlet to which gas is supplied at a pressure exceeding 100 kPa above ambient

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* pressures (typically less than 10 kPa), terminal *outlet* pressures (less than 600 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

[SOURCE: ISO 4135:2022, 3.1.4.24]

201.3.245
humidifier
device that adds water in the form of droplets or vapour, or both, to the inspired gas

Note 1 to entry: This term includes vaporising, bubble-through and ultrasonic *humidifiers* and active *heat and moisture exchangers*.

[SOURCE: ISO 4135:2022, 3.7.2.1]

201.3.246
I:E ratio
ratio of the *inspiratory time* to the expiratory time in a *respiratory cycle*

[SOURCE: ISO 19223:2019, 3.4.19, modified — deleted notes.]

201.3.247
immunity
the ability of *ME equipment* or an *ME system* to perform without degradation in the presence of an electromagnetic disturbance

[SOURCE: IEC 60601-1-2:2014+AMD1:2020, 3.8]

201.3.248
inflation
ventilator action intended to increase the volume of gas in the *lungs* by the application of an elevated-pressure waveform to the *patient-connection port* until a specified termination criterion is met

[SOURCE: ISO 19223:2019, 3.3.1, modified — deleted notes.]

201.3.249
inflation phase
interval from the start of the rise in *airway pressure* resulting from the initiation of an *inflation* to the start of the expiratory flow resulting from its termination

[SOURCE: ISO 19223:2019, 3.4.10, modified — deleted notes.]

201.3.250
inflation-type
inflation characterized by its temporal delivery pattern following initiation, and its termination criteria

[SOURCE: ISO 19223:2019, 3.3.2, modified — deleted notes.]

201.3.251
information supplied by the manufacturer
information related to the identification and use of a medical device or *accessory*, in whatever form provided, intended to ensure the safe and effective use of the medical device or *accessory*

Note 1 to entry: For the purposes of this document, *e-documentation* is included in *information supplied by the manufacturer*.

Note 2 to entry: For the purposes of this document, shipping documents and promotional material are excluded from *information supplied by the manufacturer.* However, some *authorities having jurisdiction* can consider such supplemental information as *information supplied by the manufacturer*.

Note 3 to entry: The primary purpose of *information supplied by the manufacturer* is to identify the medical device and its *manufacturer*, and provide essential information about its safety, performance, and appropriate use to the user or other relevant persons.

[SOURCE: ISO 20417:2021, 3.10, modified — deleted note 4.]

201.3.252
inspiratory time
t_I
duration of an *inflation phase* or inspiratory phase

[SOURCE: ISO 19223:2019, 3.4.8, modified — deleted notes.]

201.3.253
inspiratory volume
V_{insp}
volume of gas delivered through the *patient-connection port* during an *inspiratory phase* or *inflation phase*

[SOURCE: ISO 19223:2019, 3.8.3, modified — deleted notes.]

201.3.254
instructions for use
IFU
portion of the *accompanying information* that is essential for the safe and effective use of a medical device or *accessory* directed to the user of the medical device

Note 1 to entry: For the purposes of this document, a user can be either a *lay* user or professional user with relevant specialized training.

Note 2 to entry: For the purposes of this document, instructions for the professional *processing* between uses of a medical device or *accessory* can be included in the *instructions for use*.

Note 3 to entry: The *instructions for use,* or portions thereof, can be located on the display of a medical device or *accessory*.

Note 4 to entry: Medical devices or *accessories* that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some *authorities having jurisdiction*.

[SOURCE: ISO 20417:2021, 3.11, modified — deleted note 5.]

201.3.255
intelligent alarm system
alarm system that makes logical decisions based on monitored information without *operator* intervention

EXAMPLE 1 An *alarm system* that changes priority based on the rate of change of a monitored variable.

EXAMPLE 2 An *alarm system* that suppresses an *alarm condition* when a related *alarm condition* of higher priority has recently generated an *alarm signal*.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.24]

201.3.256
latching alarm signal
alarm signal that continues to be generated after its triggering event no longer exists until stopped by deliberate *operator* action

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.26]

201.3.257
lay
<adj> term referring to non-professional or professional without relevant specialized training

EXAMPLE *Lay operator*, *lay responsible organization*.

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.2]

201.3.258
low-pressure hose assembly
assembly consisting of a flexible hose with permanently attached gas-specific *inlet* and *outlet connectors* and designed to conduct a *medical gas* at pressures less than 1 400 kPa

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* pressures (typically less than 10 kPa), terminal *outlet* pressures (less than 1 400 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

[SOURCE: ISO 4135:2022, 3.2.3.1]

201.3.259
lung
each of the pair of compliant organs within the ribcage (thorax) bounded by the terminal bronchiole and the visceral pleura, which during *ventilation* provide gas/blood interfaces that enable oxygen from the gas to pass into the blood and carbon dioxide to be removed

[SOURCE: ISO 19223:2019, 3.1.16, modified — deleted notes.]

201.3.260
manual ventilation port
port to which a manual inflating device can be connected

201.3.261
marking
information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a medical device or *accessory*

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, *marking* is different from 'direct *marking*' as commonly described in unique device identification (UDI) standards and regulations. A UDI 'direct *marking*' is a type of *marking*.

[SOURCE: ISO 20417:2021, 3.16, modified — deleted note 3.]

201.3.262
mask
device which provides a non-invasive interface between the *patient's airway* and a *patient-connection port* or other connection to a source of respirable gas

[SOURCE: ISO 4135:2022, 3.8.6.4]

201.3.263
maximum limited pressure
$P_{lim,max}$
highest *airway pressure* that can occur during *normal use* or under *single fault condition*

[SOURCE: ISO 4135:2022, 3.1.4.41.3]

201.3.264
medical gas pipeline system
combination of a supply system, monitoring and *alarm system* and a pipeline distribution system with terminal units for provision of medical gases or vacuum

[SOURCE: ISO 4135:2022, 3.2.1.1]

201.3.265
monitoring equipment
equipment or part that measures and indicates the value of a variable to the *operator*

Note 1 to entry: *Monitoring equipment* includes devices that are not electrical in operation, such as a pressure gauge.

Note 2 to entry: The value can be displayed continuously or intermittently.

Note 3 to entry: The *monitoring equipment* can be primarily intended for detection of an *alarm condition* or for external communication.

[SOURCE: ISO 4135:2022, 3.11.1.3, modified —replaced "user" with "*operator*".]

201.3.266
operator interface
means by which the *operator* and the *ME equipment* interact

Note 1 to entry: The *accompanying documents* are considered part of the *ME equipment* and its *operator interface*.

Note 2 to entry: *Operator interface* includes all the elements of the *ME equipment* with which the *operator* interacts including the physical aspects of the *ME equipment* as well as visual, auditory, tactile displays and is not limited to a software interface.

Note 3 to entry: For the purposes of this standard, the *manufacturer* may treat the combination of *ME equipment* and other equipment as a single *operator interface*.

Note 4 to entry: See IEC 62366-1:2015+AMD1:2020, 3.26.

[SOURCE: IEC 60601-1-6:2010+AMD2:2020, 3.1]

201.3.267
outlet
opening through which gas leaves a device or component

[SOURCE: ISO 4135:2022, 3.1.4.40]

201.3.268
patient-connection port
port of a *breathing system* intended for connection to an *airway device*

Note 1 to entry: The *patient-connection port* is the end of the *breathing system* proximal to the *patient*.

Note 2 to entry: The *patient-connection port* is typically a *connector* suitable for connection to an *airway device* such as a tracheal tube, tracheostomy tube, face *mask* or supralaryngeal airway.

Note 3 to entry: Current product standards typically specify that the *patient-connection port* is required to be in the form of specific standardized *connectors*, for example, a *connector* conforming to ISO 5356-1.

[SOURCE: ISO 4135:2022, 3.1.4.41, modified —deleted note 4.]

201.3.269
PEEP
positive end-expiratory pressure
<actual and measured value> respiratory pressure at the end of an *expiratory phase*

[SOURCE: ISO 19223:2019, 3.10.4, modified — deleted notes.]

201.3.270
physiologic closed-loop control system
part of *ME equipment* or *ME system* used to adjust a physiologic variable relative to a command variable using a feedback variable

[SOURCE: IEC 60601-1-10:2007+AMD2:2020, 3.19]

201.3.271
pressure-control
inflation-type that acts to generate a constant inspiratory pressure at a set level, after a set rise time

[SOURCE: ISO 19223:2019, 3.3.4, modified — deleted notes.]

201.3.272
processing
<preparation of medical device, *accessory*> activity to prepare a new or used medical device and *accessory* for its *intended use*

[SOURCE: ISO 20417:2021, 3.20]

201.3.273
professional healthcare facility
facility that is continually staffed by suitably trained *healthcare professional operators*

EXAMPLE Hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services

Note 1 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

201.3.274
protection device
part or function of *ME equipment* that, without intervention by the *operator*, protects the *patient* from hazardous output due to incorrect delivery of energy or substances

201.3.275
respiratory cycle
complete sequence of respiratory events that leads to an increase, followed by a corresponding decrease, of gas volume in the *lung* regardless of how it is generated

[SOURCE: ISO 19223:2019, 3.4.16, modified — deleted notes.]

201.3.276
security level
level corresponding to the required set of countermeasures and inherent *cybersecurity* properties of devices and systems for a zone or conduit based on assessment of *risk* for the zone or conduit

[SOURCE: IEC/TR 60601-4-5:2021, 3.23]

201.3.277
set rate
number of assured *inflations* that are set to occur in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.1, modified — deleted notes and examples.]

201.3.278
single use
<medical device, *accessory*> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

Note 1 to entry: A *single use* medical device or *accessory* is not intended by its *manufacturer* to be further *processed* and used again.

[SOURCE: ISO 20417:2021, 3.27]

201.3.279
software item
any identifiable part of a computer program, i.e., source code, object code, control code, control data, or a collection of these items

Note 1 to entry: Three terms identify the software decomposition. the top level is the software system. the lowest level that is not further decomposed is the software unit. All levels of composition, including the top and bottom levels, can be called *software items*. a *software system*, then, is composed of one or more *software items*, and each *software item* is composed of one or more software units or decomposable *software items*. The responsibility is left to the *manufacturer* to provide the definition and granularity of the *software items* and software units.

[SOURCE: IEC 62304:2006+AMD1:2015, 3.25, modified — deleted note 2.]

201.3.280
spontaneous breath rate
total number of spontaneous breaths initiated in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.3, modified — deleted notes.]

201.3.281
standard temperature and pressure dry
STPD
pressure of 101,325 kPa at a temperature of 20 °C, dry

[SOURCE: ISO 4135:2022, 3.1.1.8]

201.3.282
sterile
free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.29]

201.3.283
sterilization
process used to render product free from viable microorganisms

Note 1 to entry: In a *sterilization process*, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: ISO 17664-1:2021, 3.17]

201.3.284
suction catheter
flexible tube designed for introduction into the respiratory tract or an *airway device* to remove material by suction

[SOURCE: ISO 8836:2019, 3.17]

201.3.285
symbol
graphical representation appearing on the label or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

Note 1 to entry: The *symbol* can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters (with sufficient justification).

[SOURCE: ISO 20417:2021, 3.30]

201.3.286
system recovery
method for fault handling via an automatic restart of *PESS* for parts of the *ME equipment* or for the complete *ME equipment*

Note 1 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

201.3.287
technical alarm condition
alarm condition arising from a monitored equipment-related or *alarm system*-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artefact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.36]

201.3.288
technical description
portion of the *accompanying information* directed to the *responsible organization* and *service personnel* that is essential for preparation for the first use and safe use, maintenance or repair as well as *processing* transport or storage for the expected lifetime of a medical device

Note 1 to entry: The *technical description* may be included in the *instructions for use*.

[SOURCE: ISO 20417:2021, 3.30, modified — deleted note 2.]

201.3.289
tidal volume
V_T
volume of gas that enters and leaves the *lung* during a breath

[SOURCE: ISO 19223:2019, 3.8.1, modified — deleted notes.]

201.3.290
total respiratory rate
number of *respiratory cycles* in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.2, modified — deleted notes.]

201.3.291
transit-operable
<adj> term referring to transportable equipment whose *intended use* includes operation while it is being moved

EXAMPLE Transportable *ME equipment* that is body-worn, hand-held, attached to a wheelchair, or used in a car, bus, train, boat or plane.

Note 1 to entry: For the purpose of this standard, *transit-operable* use in the *home healthcare environment* can include use indoors, outdoors and in vehicles.

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.4]

201.3.292
use scenario
specific sequence of tasks performed by a specific *operator* in a specific use environment and any resulting response of the *ME equipment*

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.22, modified — replaced "user" with "*operator*" and "medical device" with "*ME equipment*".]

201.3.293
validation
confirmation, through the provision of *objective evidence*, that the requirements for a specific *intended use* or application have been fulfilled

Note 1 to entry: The *objective evidence* needed for a *validation* is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word "*validated*" is used to designate the corresponding status.

Note 3 to entry: The use conditions for *validation* can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

201.3.294
ventilation
cyclical movement of a respirable gas into and out of the *lungs*

Note 1 to entry: This might be by external or spontaneous means, or by a combination of both.

[SOURCE: ISO 19223:2019, 3.1.9, modified — deleted note 2.]

201.3.295
ventilation-mode
specified manner in which a *ventilator* performs its ventilatory function when connected to a *patient*

[SOURCE: ISO 19223:2019, 3.11.2, modified — deleted notes.]

201.3.296
ventilator
medical device or *medical electrical equipment* intended to provide *artificial ventilation*

[SOURCE: ISO 19223:2019, 3.1.1, modified — deleted notes.]

201.3.297
ventilator breathing system
VBS
pathways through which gas flows to or from the *patient* at respiratory pressures, bounded by the port through which respirable gas enters, the *patient-connection port* and the gas *exhaust port*

Note 1 to entry: These pathways typically extend within and outside the body of the *ventilator*, with those outside being *operator*-detachable.

Note 2 to entry: The *port* of entry of a respirable gas into the *ventilator breathing system* can be inside the body of the *ventilator* and should not be confused with an external connection port into which respirable gas enters before being reduced to respirable pressures.

[SOURCE: ISO 19223:2019, 3.1.18, modified — deleted notes 3 and 4.]

201.3.298
ventilator-dependent
<*patient*> dependent upon *artificial ventilation* in order to prevent serious deterioration of health or death

Note 1 to entry: A *ventilator-dependent patient* cannot breathe well enough to maintain life-sustaining levels of oxygen and carbon dioxide in the blood. For the purposes of this document, dependent means the loss of therapy can require immediate medical intervention.

EXAMPLE *Patients* with Duchenne muscular dystrophy or other degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life.

201.3.299
volume-control
inflation-type that generates inspiratory flow to a selected flow-waveform, for a set *inspiratory-time*, or until the set volume has been delivered

[SOURCE: ISO 19223:2019, 3.3.3, modified — deleted notes.]

201.4 General requirements

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 4 applies, except as follows:

Addition:

201.4.3.101 Additional requirements for *essential performance*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

Additional *essential performance* requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
Delivery of *ventilation* at the *patient-connection port* within the *alarm limits* set by the *operator* or	[a]
generation of an *alarm condition*	
airway pressure	201.12.4.102
continuing positive-pressure	201.12.4.110
functional connection failure	201.13.2.103
high *airway pressure*	201.12.4.106
high leakage	201.12.4.111
hypoventilation	201.12.4.109
internal electrical power source nears depletion	211.8.4.101
low expired volume[b], if provided	201.12.4.103
obstruction	201.12.4.107
oxygen levels[c], if provided	201.12.4.101
system recovery	201.4.3.102
tidal volume	201.12.1.105

[a] 202.4.3.1 and 202.8.1.101 indicate methods of evaluating delivery of *ventilation* as acceptance criteria following specific tests required by ISO 80601 series.

[b] If $etCO_2$ monitoring or high leakage is not in use.

[c] If a control for the setting of the inspiratory oxygen concentration is provided.

201.4.3.102 *System recovery*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) Following a malfunction, which causes loss or degradation of *essential performance*, the *ventilator* shall attempt to perform a *system recovery* with the intention of restoring the *essential performance* of the *ventilator*.

NOTE 2 A *ventilator* or a subassembly function can become disturbed by a malfunction that could jeopardize the *essential performance* of the *ventilator*. Without *system recovery*, the *patient* would have to be disconnected and connected to an alternative means of *ventilation*. *Ventilation* would thus be interrupted until an alternative means of *ventilation* is connected. *System recovery,* as specified in this subclause, attempts to automatically re-establish *ventilation* in a shorter period. If necessary, the *ventilator* can be replaced later when it is less consequential for the *patient's* therapy.

b) *System recovery* may result in the temporary:

1) cessation in the *ventilation* of the *patient*; or

2) reduction in the function of *ventilator* subassemblies without impacting the *ventilation* of the *patient.*

EXAMPLE The temporary blanking of the display.

c) During a *system recovery* with a cessation of *ventilation*:

1) the *ventilator* shall allow spontaneous *patient* breathing in accordance with 201.103; and

2) the *ventilator* shall be equipped with an *alarm system* to indicate *system recovery* with a cessation of *ventilation*.

i) The *system recovery* with a cessation of *ventilation alarm condition* shall be *high priority*.

d) During a *system recovery* without a cessation of *ventilation*, the *ventilator* shall be equipped with an *alarm system* to indicate *system recovery* without a cessation of *ventilation*.

1) The *system recovery* without a cessation of *ventilation alarm condition* shall be at least *low priority*.

2) A *low priority system recovery* without a cessation of *ventilation alarm condition* need not have an auditory *alarm signal*.

e) Following a *system recovery* without *operator* intervention, the *ventilator* shall attempt to operate with the same system configuration settings, *ventilation* settings and *alarm settings* as before the *system recovery*.

1) If the system configuration settings, ventilation settings or *alarm settings* are different after the *system recovery*, the *ventilator* shall be equipped with an *alarm system* to indicate any change in settings.

2) The change in settings *alarm condition* shall be at least *medium priority*.

f) The duration of a *system recovery* with a cessation of *ventilation* should be as short as practicable to avoid an unacceptable *risk* to the *patient*.

g) The maximum duration of a *system recovery* of ventilation shall be disclosed in the *instructions for use*.

Check conformity by inspection of the *instructions for use* and functional testing.

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

In the *risk management file*, the *manufacturer* shall:

aa) state the probability of hardware-component failure that results in the *ventilator* needing to be taken out of service during the *expected service life* assuming that the preventative inspection, maintenance and calibration are performed according to the *accompanying documents*; and

bb) summarize the methodology used to determine this probability.

201.4.5 Alternative *risk control* measures or test methods for *ME equipment* or *ME system*

Amendment (add prior to the compliance check):

aa) Subsequent revisions of dated references (new editions or amendments) may be used in substitution of a referenced document provided the *manufacturer* can demonstrate the *hazard* or *hazardous situation* addressed in the dated normative reference is adequately resolved in the subsequent revision.

201.4.6 *ME equipment* or *ME system* parts that contact the *patient*

Amendment (add at end of 4.6 prior to the compliance check):

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

aa) The *VBS* or its parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* according to this subclause.

201.4.10.2 *Supply mains* for *ME equipment* and *ME systems*

Replacement of the tenth dash as follows.

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

— For operation from:

1) 12 V d.c. *supply mains*

   i) the *rated* range shall include at least 11,6 V to 15,1 V, and

   ii) the *ME equipment* shall maintain *basic safety* and *essential performance* during and following a 30 s dip to 10 V.

2) 24 V d.c. *supply mains*

   i) the *rated* range shall include at least 23,2 V to 30,3 V, and

   ii) the *ME equipment* shall maintain *basic safety* and *essential performance* during and following a 30 s dip to 20 V.

3) other d.c. *supply mains*

   i) a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple not exceeding 10 % of the average value.

Additional subclauses:

201.4.11.101 Additional requirements for pressurized gas input

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

201.4.11.101.1 Overpressure requirement

a) A *ventilator* with a *high-pressure inlet* shall

   1) operate and meet the requirements of this document throughout its *rated* range of input pressure; and

   2) not cause an unacceptable *risk* under the *single fault condition* of 1 000 kPa.

b) If the *ventilator* has a maximum *rated* input pressure in excess of 600 kPa, the *ventilator* shall not cause an unacceptable *risk* under the *single fault condition* of twice the maximum *rated* input pressure.

NOTE 1 Internal pressure regulators can be needed to accommodate the *single fault condition* of maximum input pressure, as well as the *rated* range of input pressure.

NOTE 2 Under the *single fault condition* of overpressure, it is desirable for gas to continue to flow to the *VBS*. Under this condition, the flowrate from the *ventilator* is likely to be outside of its specification.

Check conformity by functional testing in *normal use* and under *normal condition* with the most adverse operating settings, by functional testing in *single fault condition* and inspection of the *risk management file*.

201.4.11.101.2 Compatibility requirement

If the *ventilator* is intended to be connected to a *medical gas pipeline system* conforming with ISO 7396-1:2016+AMD1:2017, then

a) the *rated* range of input pressure shall cover the range specified in ISO 7396-1:2016+AMD1:2017, and

NOTE Taking account of requirements for over-pressure and under-pressure, this corresponds to a range 280 kPa to 600 kPa.

b) under *normal condition*,

1) the maximum 10 s average input flow required by the *ventilator* for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the *gas intake port*, and

2) the transient input flow shall not exceed 200 l/min averaged for 3 s

or

3) the *accompanying documents* shall disclose the following:

i) the maximum 10 s average input flow required by the *ventilator* for each gas at a pressure of 280 kPa, measured at the *gas intake port*;

ii) the maximum transient input flow averaged for 3 s required by the *ventilator* for each gas at a pressure of 280 kPa, measured at the *gas intake port*;

iii) a warning to the effect that this ventilator is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the ventilator interferes with the operation of adjacent equipment.

Check conformity by functional testing in *normal use* and under *normal condition* with the most adverse operating settings and by inspection of the *accompanying documents*.

EXAMPLE The highest driving gas consumption, the highest *fresh gas* delivery, and, if provided, the highest *rated* gas consumption at any gas power supply output under worst-case settings for *set rate* and *tidal volume* and worst-case *medical gas pipeline system* conditions within the *rated* range for inlet pressure.

201.5 General requirements for testing of *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 5 applies, except as follows.

Addition:

201.5.101 Additional requirements for general requirements for testing of *ME equipment*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

201.5.101.1 *Ventilator* test conditions

a) For testing, the *ventilator*

1) shall be connected to gas supplies as specified for *normal use*,

2) except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

b) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

201.5.101.2 Gas flowrate and leakage specifications

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

All requirements for the flowrate, volume, and leakage in this document,

a) are expressed at *STPD*,

b) except for those associated with the *VBS*, which are expressed at *BTPS*.

Correct all test measurements to STPD or BTPS, as appropriate.

201.5.101.3 *Ventilator* testing errors

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) For the purposes of this document, acceptance criteria for declared tolerances of testing shall use:

1) *procedure* 1 (calculation of uncertainty of measurement) from IEC Guide 115:2021, 4.4.2; or

2) *procedure* 2 (accuracy method) from IEC Guide 115:2021, 4.4.3.

b) Test equipment and methods shall be selected and controlled to ensure that the uncertainty (with coverage factor k = 2, for confidence of ~95%) is no more than 30% of the disclosed tolerance for the parameter being tested.

EXAMPLE If the *manufacturer* wishes to claim a tolerance for *tidal volume* of ±(10 ml +10 % of set volume) then the uncertainty of the measurement cannot exceed ±(3 ml +3 % of set volume).

c) The *manufacturer* shall disclose the measurement uncertainty of each disclosed tolerance in the *technical description*.

Check conformity by inspection of the *technical description*.

201.6 Classification of *ME equipment* and *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 6 applies.

201.7 *ME equipment* identification, *marking*, and documents

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 7 applies, except as follows.

Addition:

201.7.1.101 *Information to be supplied by the manufacturer*

a) The *information supplied by the manufacturer* of a *ventilator* and its *accessories* shall conform with ISO 20417:2021.

b) In applying ISO 20417:2021, the terms in this document and those in IEC 60601-1:2005+AMD1:2012+AMD2:2020 shall be used as follows.

1) The term "*accompanying information*" shall assume the same meaning as *accompanying documents*.

2) The term "*medical device*" shall assume the same meaning as *ME equipment*.

3) The term "*user*" shall assume the same meaning as *operator*.

4) The term "*patient*" shall include animals.

Check conformity by application of ISO 20417:2021.

201.7.2.3 Consult *accompanying documents*

Replacement:

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

The *ventilator* shall be *marked* with the safety sign for the mandatory action: "follow instructions for use", ISO 7010-M002 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.2, Number 10).

Additional subclauses:

201.7.2.4.101 Additional requirements for *accessories*

a) *Accessories* supplied separately shall:

1) fulfil the requirements of ISO 20417:2021, 6.1.1 c); and

2) be *marked* with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable. See also 201.7.2.101.

b) If *marking* the *accessory* is not practicable, this information may be placed in the *instructions for use*.

NOTE The *manufacturer* of the *accessory* can be the *ventilator manufacturer* or another entity ("third-party manufacturer", healthcare provider or durable medical equipment provider) and all these entities are expected to ensure conformity with this requirement. Additional requirements are found in 201.102.

Check conformity by inspection and inspection of the *risk management file* for any limitations or adverse effects of the *accessory*.

Additional subclauses:

201.7.2.18 Additional requirements for external gas source

Amendment (add before the first dash):

If provided with a control for the setting of the inspiratory oxygen concentration, adjacent to each input *connector*, the *ME equipment* shall be *marked* with:

a) the gas name or chemical *symbol* in accordance with ISO 5359:2014+AMD1:2017, if applicable;

b) the *rated* range of gas pressure;

c) for oxygen gas inputs, the *rated* range of oxygen concentration;

d) gas-specific colour coding in accordance with ISO 32:1977, if colour coding is used;

EXAMPLE Colour coding to match the colour of the flexible hose or a gas cylinder intended to be attached to the *connector of an inlet*.

NOTE In some countries, other colour coding is used.

201.7.2.101 Additional requirements for *marking* on the outside of *ME equipment* or *ME equipment* parts

a) If applicable, *operator*-accessible *ME equipment,* parts or *accessories* shall have *clearly legible markings* of the following.

1) for a *ventilator* intended to be used in the magnetic resonance (MR) environment, in accordance with IEC 62570:2014:

i) *symbol* 7.3.1-1 (Table 201.D.2.101, *symbol* 3) or *symbol* 7.3.1-2 of IEC 62570:2014 (Table 201.D.2.101, *symbol* 4) for an 'MR Safe' *ventilator*; or

ii) *symbol* 7.3.2 of IEC 62570:2014 (Table 201.D.2.101, *symbol* 5) for an 'MR Conditional' *ventilator.*

2) for a *ventilator* not intended for use in the magnetic resonance (MR) environment, in accordance with IEC 62570:2014 *symbol* 7.3.3 (Table 201.D.2.101, *symbol* 6) for an 'MR Unsafe' *ventilator.*

3) an arrow indicating the intended direction of gas flow:

i) for the *gas output port*; and

I) *Symbol* 0795 of ISO 7000 (Table 201.D.2.101, *symbol* 1) may be used.

ii) for the *gas return port*.

II) *Symbol* 0794 of ISO 7000 (Table 201.D.2.101, *symbol* 2) may be used.

4) for *flow-direction-sensitive components* that are *operator*-removable without the use of a *tool*, an arrow indicating the direction:

i) of the flow; or

ii) of inspiratory flow if exposed to inspiratory and expiratory flow.

b) If applicable, *operator*-accessible *ME equipment,* parts or *accessories* shall have *clearly legible markings,* on or adjacent to the following items:

1) for a *gas intake port*, a warning not to obstruct the *gas intake port*.

EXAMPLE WARNING: Gas Intake – Do not obstruct.

i) A *symbol* or *safety sign* evaluated in accordance with to IEC 62366-1 as *information for safety* may be used.

Check conformity by inspection.

201.7.4.2 Control devices

Amendment (add after the second dash):

aa) The *marking* of the trigger sensitivity control shall be such that the minimum (least *patient* effort) and the maximum (greatest *patient* effort) trigger sensitivity settings are self-evident to the *operator*.

bb) The *marking*, if numeric, shall

1) use the lowest number to represent the setting for the least *patient* effort; and

2) not only be numeric.

201.7.4.3 Units of measurement

Amendment (add to the bottom as a new row in Table 1):

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

aa) All gas volume, flow, and leakage specifications:

1) shall be expressed at *STPD*; except for those associated with the *VBS*, which

2) shall be expressed at *BTPS*.

bb) The unit of *airway pressure* measurement shall be capable of being configured to be expressed in hPa.

201.7.9.2.1 General

Amendment (add as the fifth bullet following the first paragraph):

— the intended position of the *operator*;

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

a) Separate *instructions for use* shall be provided for:

1) the *lay operator*; and

2) the supervising clinician or the *healthcare professional operator.*

b) Unless otherwise indicated in this document, the *manufacturer* may choose in which *instructions for use* to place the information required by this document based on *risk management* and *usability* considerations.

c) The supervising clinician or the *healthcare professional operator instructions for use* shall include the information contained in the *lay operator instructions for use*.

d) The *instructions for use* shall disclose the following:

1) the intended range of *tidal volume*.

Check conformity by inspection of the *instructions for use*, the *risk management file*, and *usability engineering file*.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

The *instructions for use* shall include the following.

a) A warning statement to the effect of "WARNING: To prevent death or serious injury, monitor the patient and the ventilator regularly in order to determine the need to provide emergency ventilation when an alarm sounds or the ventilator malfunctions."

b) A warning statement to the effect of "WARNING: Do not cover the ventilator or place in a position that affects proper operation", including applicable examples.

EXAMPLE 1 **WARNING**: Do not position next to a curtain that blocks the flow of cooling air, thereby causing the *ME equipment* to overheat.

EXAMPLE 2 **WARNING**: Do not block the gas intake port or emergency intake port, thereby interfering with patient ventilation.

c) A warning statement to the effect of "WARNING: Always have immediate access to an alternative means of ventilation, which is ready for use, to avoid patient death or serious injury."

EXAMPLE 3 **WARNING**: Failure to have an alternative means of ventilation such as a second *ventilator* of the same type or a self-inflating, manually powered resuscitator (as specified in ISO 10651-4) with *mask* can result in *patient* death if the *ventilator* fails.

d) A warning statement to the effect of "WARNING: Do not add any attachments or accessories to the ventilator that contravene the instruction for use of the ventilator or accessory, as the ventilator might not function correctly which consequently can result in patient death."

NOTE 2 There is guidance or rationale for this subclause contained in Clause AA.2.

e) If the *instructions for use* include a *VBS* configuration with a *BSF* exposed to the humidity from nebulisation or humidification, a warning statement to the effect of "WARNING: When using nebulisation or humidification, the breathing system filter will require more frequent replacement to prevent increased resistance or blockage."

NOTE 3 There is guidance or rationale for this subclause contained in Clause AA.2.

f) A warning statement to the effect of "WARNING: Do not use the ventilator at an altitude above (insert maximum *rated* altitude) or outside a temperature of [insert *rated* temperature range]. Using the ventilator outside of this temperature range or above this altitude can affect the ventilator performance which consequently can result in patient death."

g) A warning statement to the effect of "WARNING: Do not connect the ventilator to the battery of a battery-powered wheelchair unless the connection is listed in the instruction for use of the ventilator or wheelchair as this can affect the ventilator performance which can consequently result in patient death."

NOTE 4 There is guidance or rationale for this subclause contained in Clause AA.2.

h) A warning statement to the effect of "WARNING: When using the ventilator in a carrying case, only use a carrying case that is listed in the instructions for use to prevent adverse ventilator performance which can consequently result in patient death."

i) A warning statement to the effect of "WARNING: To reduce the likelihood of disconnection and to prevent adverse ventilator performance, use only accessories compatible with the ventilator. Compatibility is determined by reviewing the instructions for use of either the ventilator or the accessories".

j) If applicable, a warning statement to the effect of "WARNING: The ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser."

k) If applicable, a warning statement to the effect of "WARNING: Unintentional leaks cause indicated volume and expired CO_2 values to differ from actual patient values."

Check conformity by inspection of the *instructions for use*.

201.7.9.2.8.101 Additional requirements for start-up *procedure*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

NOTE 2 For the purposes of this document, a start-up *procedure* is a pre-use functional test that is used to determine whether the *ventilator* is ready for use.

a) The *instructions for use* for the *lay operator* shall disclose a method by which the following can be functionally tested to determine if they are operating correctly:

   1) the assembled breathing tubes and related *accessories;*

   2) the switchover to and operation from the *internal electrical power source*; and

   3) all of the *alarm signals*, including the *alarm signals* from *distributed alarm systems*.

b) Portions of these test methods may:

   1) be performed automatically by the *ventilator*; or

   2) require *operator* action.

   EXAMPLE 1 Combination of the power-on self-test routines and *operator* actions that functionally check the *alarm signals*.

c) The specifications of any required *accessories* or test equipment needed to perform these tests shall be disclosed in the *instructions for use* for the *lay operator*.

   EXAMPLE 2 Volume, resistance, and compliance of the test lung necessary to perform the tests.

d) The *instructions for use* for the supervising clinician or the *healthcare professional operator* shall disclose a method by which all functions and settings necessary for *normal use* can be functionally tested to determine if they are operating correctly.

e) Portions of this test method may:

   1) be performed automatically by the *ventilator*; or

   2) require *operator* action.

Check conformity by inspection of the *instructions for use*.

201.7.9.2.9.101 Additional requirements for operating instructions

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

201.7.9.2.9.101.1 *Lay operator* operating instructions

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

The *instructions for use* intended for the *lay operator* shall include the following:

a) the conditions under which the *ventilator* maintains the accuracy of controlled and displayed variables as disclosed in the *instructions for use*;

EXAMPLE 1 Acceptable range of water level in a *humidifier*.

EXAMPLE 2 Interval of calibration of a flow sensor.

b) an explanation of the meaning of the IP classification *marked* on the *ME equipment;*

c) an indication as to whether the *ventilator* is intended for non-invasive *ventilation*;

EXAMPLE 3 *Mask ventilation*.

d) a description of how at least the following *alarm conditions* can be tested:

NOTE 2 There is guidance or rationale for this list item contained in Clause AA.2.

1) high leakage;

2) *internal electrical power source* nears depletion;

3) low *airway pressure*;

4) low inspiratory pressure;

5) obstruction;

6) power failure of external mains;

7) power failure of external DC power

e) a description of how the following *alarm conditions*, if provided, can be tested:

1) low expired volume;

2) oxygen levels

f) a description of a means to determine the operation time of the *internal electrical power source*;

g) a description of how to connect and test the connection of a *distributed alarm system.*

Check conformity by inspection of the *instructions for use*.

201.7.9.2.9.101.2 Supervising clinician or *healthcare professional operator* operating instructions

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) The *instructions for use* intended for the supervising clinician or the *healthcare professional operator* shall include a detailed description of the function of all *ventilation-modes* provided by the *ventilator*, including but not limited to, the following items:

1) working principle of each of the *ventilator's ventilation-modes* including waveforms;

2) methods for controlling the cycling;

3) parameter settings;

4) range of parameter settings;

5) any limitation of parameter settings;

6) a description of how at least the following *alarm conditions*, if included, can be tested:

NOTE 2 There is guidance or rationale for this list item contained in Clause AA.2.

i) continuing positive-pressure;

ii) *tidal volume*;

iii) high *airway pressure*;

iv) high expiratory volume;

v) hypoventilation; and

vi) low expiratory volume.

b) The *instructions for use* intended for the supervising clinician or the *healthcare professional operator* shall include the *rated* range of the following characteristics of the assembled *operator*-detachable parts of the *VBS*, over which the accuracies of set and monitored volumes and pressures are maintained:

1) inspiratory *gas pathway* resistance;

2) expiratory *gas pathway* resistance;

3) compliance.

4) These specifications may be presented in ranges.

5) The accuracies of set and monitored volumes may be presented as a function of these characteristics.

NOTE 3 Compliance and resistance can be nonlinear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min, maximum flowrate, or the maximum pressure).

c) If applicable, *instructions for use* intended for the supervising clinician or the *healthcare professional operator* shall disclose

1) the essential technical characteristics of each recommended *breathing system filter*, and

EXAMPLE Dead space and resistance.

2) a statement as to whether any portion of the gas supplied to a *high-pressure inlet* is supplied to the *patient.*

d) For a *ventilator* that is not provided with a control for the setting of the inspiratory oxygen concentration, the length of time required for an increase of oxygen concentration in the *tidal*

volume from room air to reach 90 % of the stable achievable delivered oxygen concentration shall be disclosed in the *instructions for use*.

1) The time shall be reported separately, as appropriate, for each *VBS* configuration (insertion point of oxygen into the *VBS*) and at *tidal volume* range indicated in the *instructions for use* when the oxygen source is greater than 99 % oxygen.

2) The *instructions for use* shall indicate that when the oxygen source is from an oxygen concentrator, the time can be significantly longer.

Check conformity by inspection of the *instructions for use*.

201.7.9.2.12 *Cleaning*, *disinfection*, and *sterilization*

Amendment: (add after normal use)

and *single fault condition*

Amendment: (add after bulleted list)

e) The *instructions for use* shall identify any portions of the *gas pathways* through the *ventilator* that can become contaminated with body fluids or by microbial material conveyed by the expired gases during both *normal condition* and *single fault condition*.

Additional subclauses:

201.7.9.2.13.101 Additional requirements for maintenance

The *instructions for use* shall disclose the following:

a) a description of periodic visual safety inspections that should be performed by the *operator*;

b) the *internal electrical power source* care and maintenance *procedures*, including instructions for recharging and replacement.

Check conformity by inspection of the *instructions for use*.

201.7.9.2.14.101 Additional requirements for *accessories*, supplementary equipment, used material

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) The *instructions for use* of the *ventilator* shall identify:

1) at least one set of *accessories*;

2) if applicable, the *ME equipment* necessary for the *ventilator's intended use*; and

3) all *accessories* that the *ventilator manufacturer* claims are compatible.

b) If applicable, the *instructions for use* of the *ventilator* shall disclose the following.

1) Any restrictions on the positioning of components within the *ventilator breathing system.*

EXAMPLE Where such components are *flow-direction-sensitive components*.

2) Any adverse effect of any recommended *accessory* on the *essential performance* or *basic safety* of the *ventilator*.

Check conformity by inspection of the *instructions for use* and inspection of the *risk management file* for any adverse effect of any recommended *accessory*.

201.7.9.3.1.101 Additional general requirements

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

The *technical description* shall disclose the following:

a) summary description of the filtering and smoothing techniques for all measured and computed variables that are displayed or used for control;

b) interdependence of control functions;

c) pneumatic diagram of the *ventilator*, including a diagram for *operator*-detachable parts of the *ventilator breathing system* either supplied or recommended in the *instructions for use*;

d) summary description of the means of initiating and terminating the *inflation phase* while in each *ventilation-mode*;

e) means by which the continuing pressure *alarm condition* is detected and a summary description of the detection algorithm; and

f) statement to the effect that the responsible organization needs to ensure the compatibility of the ventilator and all of the parts and accessories intended to be used to connect to the patient prior to use.

Check conformity by inspection of the *technical description*.

201.7.9.3.101 Additional requirements for the *technical description*

a) The *technical description* shall disclose a description of a method for checking the function of the *alarm system* for each of the *alarm conditions* specified in Table 201.101, except *system recovery*, if not performed automatically during start-up.

b) The *technical description* shall disclose which checks are performed automatically.

Check conformity by inspection of the *technical description*.

201.8 Protection against electrical *hazards* from *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 8 applies.

201.9 Protection against mechanical hazards of ME equipment and ME systems

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 9 applies, except as follows.

Additional subclause:

201.9.4.3.101 Additional requirements for instability from unwanted lateral movement

a) A *transit-operable ventilator* shall include a means by which the *ventilator* can be easily immobilized without the use of a *tool* to prevent unwanted movement during transport while in use.

EXAMPLE 1 Means to attach during transport in a personal vehicle, in an ambulance, or on a wheelchair.

b) The means shall secure the *ventilatory support equipment* so as to withstand accelerations or decelerations of 1,0 g longitudinal (forward, backward) and 1,0 g transverse (left, right) for at least 5 s in each orientation.

EXAMPLE 2 Attach the *ventilatory support equipment* to an armature at a 1 m radius from an axis of horizontal rotation. When rotating through a circle every 2 s at constant speed, the lateral (centripetal) acceleration is approximately 1,0 g. [58]

Check conformity checked by functional testing.

201.9.4.4 Grips and other handling devices

Replace list item b) with the following:

b) The *ventilator* shall be designed to include either:

1) a handle that does not require more than one hand; or

2) a carrying case or in-use bag that does not require more than one hand.

Check conformity by carrying with one hand or using the carry case or in-use bag with not more than one hand.

Additional subclause:

201.9.6.2.1.101 Additional requirements for audible acoustic energy

a) The A-weighted sound pressure level emitted by the *ventilator* shall be:

1) measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2; and

2) disclosed in the *instructions for use*.

b) The A-weighted sound power level emitted by the *ventilator* shall be:

1) calculated according to ISO 3744:2010, 8.2.2; and

2) disclosed in the *instructions for use*.

c) Check conformity with the following test:

1) Place the *ventilator* on the sound-reflecting plane and attach the least favourable *VBS* from those indicated in the *instructions for use*.

NOTE 1 The least favourable *VBS* configuration can vary by *ventilation-mode*, *inflation-type*, and flow pattern, as applicable.

2) If a *humidifier* is provided with the *ventilator*, include the *humidifier* filled to the least favourable level in the test.

3) Configure the test lung with the compliance and resistance components whose values are indicated in Table 201.102.

i) Acoustically isolate the test lung by a suitable means so that any noise caused by the test lung does not interfere with the sound measurement of the *ventilator*.

ii) Connect the *patient-connection port* to the test lung.

Table 201.102 — Test conditions for acoustic tests

Adjustable parameter	Test condition		
	For a *ventilator* intended to provide *tidal volume*		
	$V_T \geq 300$ ml	300 ml $\geq V_T \geq 50$ ml	$V_T \leq 50$ ml
Tidal volume, V_T[a]	500 ml	150 ml	30 ml
Set rate	10 breaths/min	20 breaths/min	30 breaths/min
I:E ratio	1:2	1:2	1:2
BAP	10 hPa (10 cmH_2O)	10 hPa (10 cmH_2O)	10 hPa (10 cmH_2O)
Linear resistance, R[b][39][52][55]	5 hPa·(l/s)$^{-1}$ ±10 %	20 hPa·(l/s)$^{-1}$ ±10 %	50 hPa·(l/s)$^{-1}$ ±10 %
Isothermal compliance, C[b]	50 ml·hPa^{-1} ±10 %	20 ml·hPa^{-1} ±10 %	1 ml·hPa^{-1} ±10 %

[a] V_T is measured by means of a pressure sensor on the test lung, where $V_T = C \cdot (P_{max} - P_{min})$, and
V_T is the volume delivered to the test lung
C is the isothermal compliance of the test lung
P_{max} is the maximum pressure measured in the test lung at the end of *inflation phase*
P_{min} is the minimum pressure measured in the test lung at the end of *expiratory phase*.

[b] The accuracy for C and R applies over the ranges of the measured parameters.

4) Set the *ventilator* to the least favourable *ventilation-mode*, *inflation-type*, and flow pattern, as applicable, that generates *ventilation* as indicated in Table 201.102.

NOTE 2 The least favourable *ventilation-mode*, *inflation-type*, and flow pattern can vary by *VBS* configuration.

5) Using the microphone of the sound level meter conforming with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the maximum time-weighted sound pressure levels using frequency weighting A and the time weighting F of the sound level meter (i.e. L_{AFmax}) at ten positions in a hemisphere with a radius from the geometric centre of the *ventilator* in a free field over a reflecting plane as specified in ISO 3744:2010, 8.1.1. Average the values in conformity with 8.2.2 of ISO 3744:2010.

6) Calculate the A-weighted sound pressure level averaged over the measurement surface in accordance with ISO 3744:2010, 8.2.2.

7) Calculate the A-weighted sound power level in accordance with ISO 3744:2010, 8.6.

8) Confirm that the criteria for background noise specified in 4.2 of ISO 3744:2010 are fulfilled.

9) Ensure that the average measured sound pressure level is less than that disclosed in the *instructions for use*.

10) Ensure that the sound power level is less than that disclosed in the *instructions for use.*

201.10 Protection against unwanted and excessive radiation *hazards*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 10 applies.

201.11 Protection against excessive temperatures and other *hazards*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 11 applies, except as follows.

201.11.1.2.2 *Applied parts* not intended to supply heat to a *patient*

Amendment (add between the existing paragraphs):

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

In *normal use* and *single fault conditions* and over the *rated* flowrate range and at the maximum *rated* operating temperature, the temperature of the gas delivered by the *ventilator* at the *patient-connection port,* both with and without each *humidifier* specified for use in the *instructions for use*, when averaged over 120 s, shall not exceed:

aa) 70 °C; and

bb) an energy equivalent to 43 °C and 100 % relative humidity (a specific enthalpy not to exceed 197 kJ/kg dry air).

Table 201.103 contains examples of combinations of temperature and relative humidity with such a specific enthalpy.

Table 201.103 — Examples of permissible combinations of temperature and relative humidity

Temperature °C	Relative humidity %
43	100
44	95
45	90
48	76
50	69
55	52
60	40
65	30
70	23

201.11.6.6 *Cleaning* and *disinfection* of *ME equipment* or *ME system*

Amendment (add additional requirement as new first paragraph):

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

aa) *Gas pathways* through the *ventilator* and its *accessories* not intended for *single use* that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition* shall be designed to allow for:

1) *cleaning* and *disinfection;* or

2) *cleaning* and *sterilization*.

NOTE 101 Additional requirements are found in 11.6.7 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020, Clause 8).

bb) Dismantling or parts replacement may be performed.

cc) *Processing* instructions for the *gas pathways* of the *ventilator* and its *accessories* shall:

1) conform with ISO 17664-1:2021;

2) conform with ISO 14937:2009, if applicable; and

3) be disclosed in the *instructions for use*.

Amendment (add additional requirement and replace the compliance test):

dd) *Ventilator enclosures* shall be designed to allow for surface *cleaning* and *disinfection* to reduce to acceptable levels the *risk* of infection of *operators*, bystanders, or the *patient*.

NOTE 102 ISO 14159 provides guidance for the design of *enclosures*.

ee) *Processing* instructions for the *ventilator enclosure* shall

1) conform with ISO 17664-2:2021; and

2) be disclosed in the *instructions for use*.

Check conformity by inspection of the *risk management file*. When conformity with this document could be affected by the *cleaning* or the *disinfecting* of the *ventilator* or its parts or *accessories*, clean and disinfect them the number of cycles determined by the *expected service life* in accordance with the methods indicated in the *instruction for use*, including any cooling or drying period. After these *procedures*, ensure that *basic safety* and *essential performance* are maintained. Confirm that the *manufacturer* has evaluated the effects of multiple *processing* cycles and the effectiveness of those cycles.

NOTE 103 Additional information regarding the order of test is found in 211.10.1.1.

201.11.6.7 *Sterilization* of *ME equipment* or *ME system*

Amendment (add note before compliance test):

NOTE 100 Additional requirements are found in IEC 60601–1:2005+AMD1:2012+AMD2:2020, 11.6.6, and IEC 60601-1-11:2015+AMD1:2020, Clause 8.

201.11.7 *Biocompatibility* of *ME equipment* and *ME systems*

Amendment (add after existing text prior to the conformity statement):

aa) The *manufacturer* of a *ventilator, VBS*, its parts or *accessories* shall address in the *risk management process* the *risks* associated with the leaching or leaking of substances into the *gas pathway*.

bb) The *gas pathways* shall be evaluated for *biocompatibility* in accordance with ISO 18562-1:2017.

Additional subclauses:

201.11.8.101 Additional requirements for interruption of the power supply/*supply mains* to *ME equipment*

a) The *ventilator* shall have a means of connection to an alternative *supply mains*.

b) The *instructions for use* shall include the following:

1) description of the means of connection;

2) *rated* voltage range;

3) *nominal* voltage;

4) maximum current required.

c) A means of connection to an automotive vehicle power source should be provided.

EXAMPLE A 12 V d.c., 100 W *connector*, or other *mains connector*.

Check conformity by inspection and inspection of the *instructions for use*.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 12 applies, except as follows.

201.12.1 Accuracy of controls and instruments

Amendment (add after existing sentence):

aa) The controls and indicators of a *ventilator* shall be *clearly legible* under the conditions specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.2, but with the subtended angle increased from '30°' to '45°' and the light level extended from the range of '100 lx to 1 500 lx' to the range of '1 lx to 10 000 lx'.

bb) The *ventilator* may provide means to reduce the visibility of its controls and indicators either automatically or by the *operator* action.

1) If provided, the *ventilator* shall automatically resume normal visibility during an *alarm condition*.

Check conformity by functional testing and application of the tests of IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.2.

Additional subclauses:

201.12.1.101 *Inflation-types*

A *ventilator* shall be equipped with at least:

a) a *volume-control inflation-type*; or

b) a *pressure-control inflation-type*.

Check conformity by inspection.

201.12.1.102 *Volume-control inflation-type*

a) If a *volume-control inflation-type* is provided, then with a *volume-control inflation-type* selected and the *ventilator* operating in *normal condition*, the accuracy as determined for the conditions specified in this document shall be disclosed in the *instructions for use*, as the maximum bias error and maximum linearity error.

EXAMPLE ±(5 ml + 10 % of the set volume)

b) This disclosure shall include at least the following:

1) maximum error of the *tidal volume* in relation to the set value;

2) maximum error of the *PEEP* in relation to the set *BAP* value;

3) if provided with a control for the setting of the inspiratory oxygen concentration, the maximum error of the inspiratory oxygen concentration (FiO_2) at the *patient-connection port* in relation to the set value.

i) The disclosed accuracies shall include the effects of the range of the *rated* input oxygen concentration.

c) All of the errors may be separately reported for the following ranges of intended *tidal volume*:

1) $V_T \geq 300$ ml;

2) 300 ml $\geq V_T \geq 50$ ml;

3) $V_T \leq 50$ ml.

d) The accuracy of the performance of the *ventilator* shall be either of the following:

1) determined for each *VBS* configuration indicated in the *instructions for use*;

2) determined for the worst-case *VBS* configurations indicated in the *instructions for use*.

NOTE 1 The worst-case *VBS* configuration can be different for each error or *nominal tidal volume*.

e) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

f) Check conformity by inspection of the *risk management file* for the rationale, if applicable, and with the following tests for *tidal volume* and end-expiratory pressure errors.

NOTE 2 In some cases, the following tests can be carried out simultaneously.

1) Set up the *ventilator* as shown in Figure 201.101.

2) If applicable, determine or input the *VBS* compliance required for compliance correction as indicated in the *instructions for use* and activate this correction. If a *humidifier* is used, fill the *humidifier* to the maximum water level prior to determining the *VBS* compliance.

3) Use the test parameters and settings of the first applicable row (selected by intended *tidal volume*) of Table 201.104.

4) Wait for steady-state conditions to be achieved.

NOTE 3 Intentionally, for some of these tests (i.e. those using a *VBS* with a large compliance and a high resistance), the *end-expiratory flow* will not reach zero.

5) Determine the *tidal volume*, for example, by integration of the flow signal provided by a calibrated flow sensor located at the *patient-connection port* or by the product of the test lung compliance and the measured change of test lung pressure, compensated, for temperature effects due to fast compression of the gas, if necessary.

NOTE 4 Additional information on the construction of an isothermal test lung is found in Reference [43].

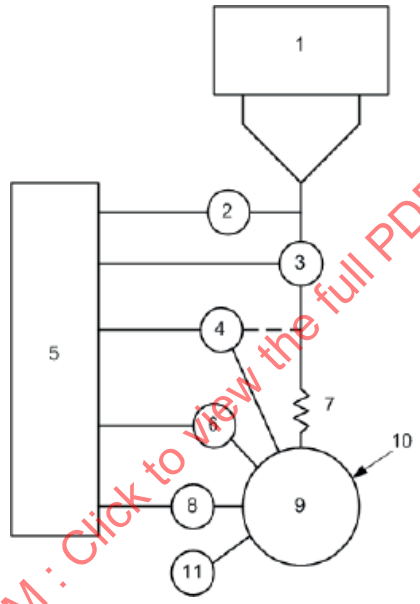
6) Compare the result with the acceptance criteria derived from the volume setting for the test and the tolerance indicated in the *instructions for use*.

7) Determine the accuracy of the *tidal volume monitoring equipment* by comparing its reading to the *tidal volume* determined in 5). Refer to 201.12.1.105.

8) Determine the *PEEP* as the average of the *airway pressure* measurements over the last 50 ms of the *expiratory phase*.

9) Compare the result with the acceptance criteria derived from the *BAP* setting for the test and the resulting difference indicated in the *instructions for use*.

10) Repeat 3) to 9) for 30 consecutive *inflations*.



Key

1 *ventilator* under test
2 pressure sensor
3 flow sensor, with a 10 % to 90 % rise time of no greater than 10 ms
4 oxygen sensor, if applicable
5 data acquisition system, with minimum sample rate of 200 samples/s
6 temperature sensor
7 test lung resistance (R_{lung})
8 pressure sensor, with a 10 % to 90 % rise time of no greater than 10 ms
9 test lung compliance (C_{lung})
10 test lung
11 artificial leakage (*pressure-control inflation-type* only)

NOTE The oxygen sensor can be placed in the *VBS*.

Figure 201.101 — Typical test setup for *volume-control* and *pressure-control inflation-type* accuracy

11) Repeat 3) to 10) for each applicable row (selected by intended *tidal volume*) of Table 201.104.

12) If a *humidifier* is included in the *VBS*, repeat the *tidal volume* tests with the minimum *humidifier* water level without re-determining the *VBS* compliance.

13) Unless it can be demonstrated that the worst-case flow pattern (e.g. constant flow, descending-ramp flow) has been selected for the tests, repeat 2) to 12) for each flow pattern available on the *ventilator*.

14) If the *ventilator* permits operation without compliance correction, repeat 2) to 13) without compliance correction.

Table 201.104 — *Volume-control inflation-type* settings

Test number	**Test lung parameters**		***Ventilator* settings**				
	Compliance (ml·(hPa)$^{-1}$) ± 10 %	**Linear resistance** [39][52][55] (hPa·(l/s)$^{-1}$) ± 10 %	***Tidal volume*** (ml)	***Set rate*** (breaths/min)	***Inspiratory time*** (s)	**FiO_2**[a] (%)	***BAP*** (hPa)
1	—[b]	—[b]	Maximum settable *tidal volume*	—[b]	—[b]	—[b]	—[b]
2	50	5	500	20	1	28	5
3	50	20	500	20	1	35	10
4	20	5	500	20	1	35	5
5	20	20	500	20	1	28	10
6	20	20	300	20	1	28	5
7	20	50	300	20	1	35	10
8	10	50	300	20	1	28	10
9	10	20	200	20	1	35	5
10	3	20	50	30	0,6	28	5
11	3	50	50	30	0,6	28	10
12	3	200	50	30	0,6	35	5
13	1	200	20	30	0,4	28	5
14	1	200	10	40	0,4	28	5
15	0,5	200	5	60	0,4	28	5
16	—[b]	—[b]	Minimum settable *tidal volume*	—[b]	—[b]	—[b]	—[b]

[a] If the *ventilator* is not provided with a control for the setting of the inspiratory oxygen concentration, room air is used.

[b] The *instructions for use* shall indicate this value.

201.12.1.103 *Pressure-control inflation-type*

a) If a *pressure-control inflation-type* is provided, then with a *pressure-control inflation-type* selected and the *ventilator* operating in *normal condition*, the accuracy as determined for the test settings and conditions specified in this document shall be disclosed in the *instructions for use* as:

1) the maximum bias error; and

2) the maximum linearity error.

EXAMPLE ±(3,0 hPa + 5 % of the set pressure) (±(3,0 cmH_2O + 5 % of the set pressure)).

b) This disclosure shall include at least:

1) the maximum error of the *airway pressure* (P_{aw}) at the end of the *inflation phase* in relation to the set value;

2) the maximum error of the *airway pressure* (P_{aw}) at the end of the *inflation phase* in relation to the set value under leak condition;

3) the maximum error of *PEEP* in relation to the set *BAP* value;

4) if provided with a control for the setting of the inspiratory oxygen concentration, the maximum error of the inspiratory oxygen concentration (FiO_2) at the *patient-connection port* in relation to the set value.

i) The disclosed accuracies shall include the effects of the range of the *rated* input oxygen concentration.

c) All of the errors may be separately reported for the following ranges of intended *tidal volume*:

1) $V_T \geq 300$ ml;

2) 300 ml $\geq V_T \geq 50$ ml;

3) $V_T \leq 50$ ml.

d) The accuracy of the performance of the *ventilator* shall be either of the following:

1) determined for each *VBS* configuration indicated in the *instructions for use*;

2) determined for the worst-case *VBS* configuration indicated in the *instructions for use*.

NOTE 1 The worst-case *VBS* configuration can be different for each error or each *nominal tidal volume* range.

e) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

f) Check conformity by inspection of the *risk management file* for the rationale, if applicable, and with the following tests for end-inspiratory and end-expiratory pressure error.

NOTE 2 In some cases, the following tests can be carried out simultaneously.

1) Set up the *ventilator* as shown in Figure 201.101.

2) If applicable, determine or input the *VBS* compliance required for compliance correction as indicated in the *instructions for use* and activate this correction. If a *humidifier* is used, fill the *humidifier* to the maximum water level prior to determining the *VBS* compliance.

3) Use the test parameters and settings of the first applicable row (selected by typical intended *tidal volume*) of Table 201.105. Wait until steady-state conditions are achieved.

NOTE 3 Intentionally, for some of these tests (i.e. those using a *VBS* with a large compliance and a high resistance), the *end-expiratory flow* will not reach zero.

4) Determine the *airway pressure* at the end of the *inflation phase* as the average over the preceding 50 ms.

Table 201.105 — *Pressure-control inflation-type* settings

Test number	Intended *tidal volume*[a] (ml)	Test lung parameters			*Ventilator* settings				
		Compliance (ml(hPa)$^{-1}$) ± 10 %	Linear [39][52][55] Resistance (hPa(l/s)$^{-1}$) ± 10 %	Leakage[b] (ml/min) ±10 %	*Set rate* (breaths /min)	*Inspiratory time*[c] (s)	Pressure[d] (hPa)	FiO_2[e] (%)	*BAP* (hPa)
1	—[f]	—[f]	—[f]	—[f]	—[f]	—[f]	Maximum settable pressure	—[f]	—[f]
2	500	50	5	0	20	1	10	28	5
3	500	50	20	0	20	1	15	35	10
4	500	20	5	0	20	1	25	35	5
5	500	20	20	0	20	1	25	28	10
6	500	50	5	5 000	20	1	25	28	5
7	500	50	20	10 000	20	1	25	35	10
8	300	20	20	0	20	1	15	28	5
9	300	20	50	0	20	1	25	35	10
10	300	10	50	0	20	1	30	35	5
111	300	20	20	3 000	20	1	25	28	5
12	300	20	50	6 000	20	1	25	35	10
13	200	10	20	0	20	1	25	28	10
14	50	3	20	0	30	0,6	15	28	5
15	50	3	50	0	30	0,6	15	28	10
16	50	3	200	0	30	0,6	25	35	5
17	20	200	20	0	30	0,4	15	28	5
18	10	200	10	0	40	0,4	15	28	5
19	5	200	5	0	60	0,4	15	28	5
20	—[f]	—[f]	—[f]	—[f]	—[f]	—[f]	Minimum settable pressure	—[f]	—[f]

[a] The volume in this column is intended to be used for the selection of the test conditions and parameters based on the intended *tidal volume* of the *ventilator*.

[b] For the purpose of this test, the *VBS* under test is set up with the leakage at a constant pressure of 20 hPa.

[c] The rise time of the *ventilator* should be set to a value that ensures that the set pressure can be reached within the *inspiratory time*.

[d] For the purposes of this test, the set pressure is relative to set *BAP* level.

[e] If the *ventilator* is not provided with a control for the setting of the inspiratory oxygen concentration, room air is used.

[f] The *instructions for use* shall indicate this value.

Compare the result with the acceptance criteria derived from the pressure setting for the test and the tolerance indicated in the *instructions for use*.

5) Determine the *tidal volume*, for example, via integration of the flow signal provided by a calibrated flow sensor located at the *patient-connection port*, or for a *ventilator* that indicates a leakage-compensated *tidal volume*, by the product of the test lung compliance and the measured change of test lung pressure compensated for temperature effects due to fast compression of the gas, if necessary.

NOTE 4 Additional information on the construction of an isothermal test lung is found in Reference [43].

6) Determine the accuracy of the *tidal volume monitoring equipment* by comparing its reading to the *tidal volume* determined in 6). Refer to Table 201.105.

7) Determine the *PEEP* as the average of the *airway pressure* measurements over the last 50 ms of the *expiratory phase*.

8) Compare the result with the acceptance criteria derived from the *BAP* setting for the test and the tolerance indicated in the *instructions for use*.

9) Repeat 2) to 9) for 30 consecutive *inflations*.

10) Repeat 2) to 10) for each applicable row (selected by intended *tidal volume*) of Table 201.105.

11) If a *humidifier* is included in the *VBS*, repeat the *airway pressure* tests with the minimum *humidifier* water level without re-determining the *VBS* compliance.

12) If the *ventilator* permits operation without compliance correction, repeat 2) to 12) without compliance correction.

g) Check conformity with the following tests for oxygen (O_2) error.

1) If provided with a control for the setting of the inspiratory oxygen concentration, the accuracy of the inspiratory oxygen concentration of the gas delivered is assessed by placing the sensor of an oxygen concentration measuring device at the *patient-connection port* or inside the test lung. If the sensor is located at the *patient-connection port*, the value of the concentration is the flow-weighted average concentration as a function of flow during the *inflation phase*.

2) Evaluate the measured oxygen concentration with the acceptance criteria derived from the oxygen setting for the test and the disclosed tolerance.

3) Compare the resulting difference with the tolerance indicated in the *instructions for use*. If the sensor is located inside the test lung, care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration. If the sensor is located in the tubing system, care should be taken to ensure that the measuring device has a sufficiently fast response to permit determination of the flow-weighted average concentration during the *inflation phase.*

NOTE 5 If the sensor is located inside the test lung, care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration.

NOTE 6 If the sensor is located in the tubing system, care should be taken to ensure that the measuring device has a sufficiently fast response to permit determination of the flow-weighted average concentration during the *inflation phase*.

NOTE 7 If the oxygen concentration measuring device has pressure dependencies, compensate for these dependencies.

4) Table 201.105 — *Pressure-control inflation-type* settingsCompare each result with the acceptance criteria derived from the oxygen setting for the test in g) 1) and tolerance indicated in the *instructions for use*.

201.12.1.104 Other *inflation*-types

a) If other *inflation-types* are provided, then with each other *inflation-type* selected and the *ventilator* operating in *normal condition*,

3) the performance at the *patient-connection port*; and

4) their acceptance criteria;

as determined by the *manufacturer,* shall be disclosed in the *instructions for use*.

5) The disclosed performance and acceptance criteria shall include the effects of the range of the *rated* input oxygen concentration.

b) All of the performance and acceptance criteria may be reported separately for the following ranges of intended *tidal volume*:

1) $V_T \geq 300$ ml;

2) 300 ml $\geq V_T \geq 50$ ml; and

3) $V_T \leq 50$ ml.

c) The acceptance criteria of the performance of the *ventilator* shall either be:

1) determined for each *VBS* configuration indicated in the *instructions for use*; or

2) determined for the worst-case *VBS* configuration indicated in the *instructions for use*.

NOTE The worst-case *VBS* configuration can be different for each error or each *nominal tidal volume* range.

3) In determining the worst-case configuration consider use with active and passive humidification.

d) If worst-case *VBS* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

e) The *technical description* shall disclose a summary of the test method and the details necessary to reproduce the test results used to test each other *inflation-type*.

Check conformity by inspection of the *instructions for use*, inspection of the *risk management file* for the rationale, if applicable, and with the tests described in the *technical description*.

201.12.1.105 *Tidal volume monitoring equipment*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) The *ventilator* shall be equipped with *tidal volume monitoring equipment.*

1) The indication of the value of the *tidal volume monitoring equipment* and associated *alarm conditions* may be disabled when the expired volume *monitoring equipment* is in use.

b) The accuracy of the *tidal volume monitoring equipment* shall be disclosed in the *instructions for use*.

c) The indicated value of *tidal volume* may be displayed on *operator* demand.

d) The *tidal volume monitoring equipment* shall be equipped with an *alarm system* that detects at least a *medium priority alarm condition* to indicate when the low *tidal volume alarm limit* is reached.

1) The *tidal volume monitoring equipment* may be equipped with an *alarm system* that starts with a *low priority alarm condition* to indicate when the *tidal volume* reaches the *alarm limit* and, if this state continues, escalates to a *medium priority alarm condition*.

2) The *tidal volume alarm limit* may be:

i) pre-adjusted;

ii) *responsible organization*-configurable;

NOTE 2 There is guidance or rationale for this list item contained in Clause AA.2.

iii) *operator*-adjustable;

iv) *ventilator*-adjustable; or

v) a combination of *operator*-adjustable and *ventilator*-adjustable.

3) If the *alarm limit* is adjustable by the *ventilator*, a summary description of the algorithm that determines the *alarm limit* value shall be disclosed in the *instructions for use*.

NOTE 3 Depending on the type of *ventilation-mode* being used, there can be more than one active *alarm limit*.

e) Check conformity with functional testing and the following.

1) Select and set up the worst-case *VBS* configuration indicated in the *instructions for use*.

EXAMPLE Minimum and maximum *VBS* compliance.

2) Confirm that the *tidal volume monitoring equipment* accuracy as measured in 201.12.1.102 a) 6) and 201.12.1.103 a) 7), as applicable, is within the accuracy disclosed in the *instructions for use*.

3) For a *VBS* that includes a *humidifier*, repeat the tests at the minimum and maximum water levels (2 sets of tests for a *humidifier*).

201.12.1.106 Response of the *ventilator* to an increase in set oxygen (O_2) concentration

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) If provided with a control for the setting of the inspiratory oxygen concentration, the length of time required for the oxygen concentration in the *tidal volume* to change from an oxygen concentration of 21 % to an oxygen concentration of 90 % of the maximum achievable delivered oxygen concentration shall be disclosed in the *instructions for use*.

b) The worst-case input oxygen concentration within the *rated* range shall be used for this test.

c) The time shall be reported separately, as appropriate, at *tidal volumes* for each intended *tidal volume* under the conditions of Table 201.106, using:

1) the worst-case *VBS;* or

2) the maximum internal volume *VBS* and

3) if *bias flow* or *continuous flow* controls are provided, at:

i) the minimum *bias flow*, or

ii) the minimum *continuous flow*.

d) The time may be reported separately for:

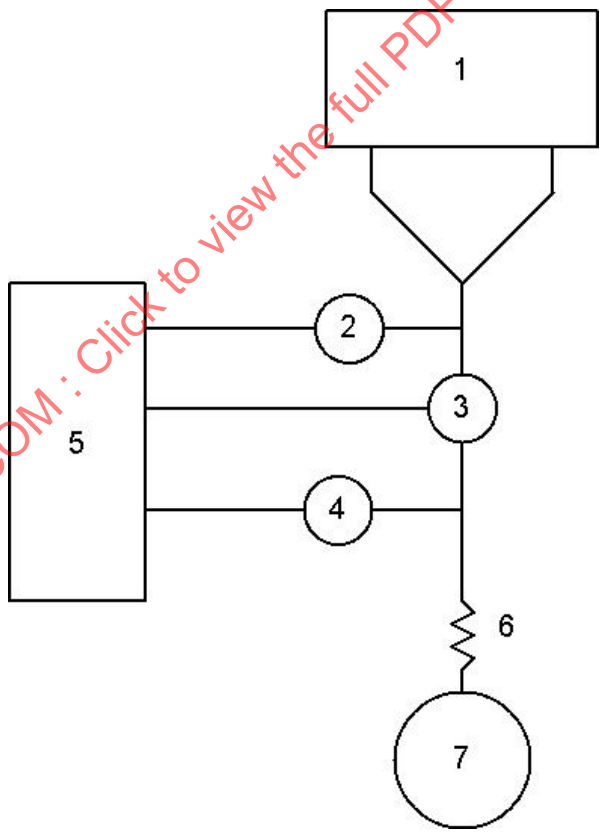
1) each *VBS;* or

2) as a maximum (for the worst-case *VBS* and minimum *tidal volume*).

e) Check conformity with the following tests:

1) Set up the *ventilator* as shown in Figure 201.102 using the worst-case *VBS* or using the maximum internal volume *VBS*. If the *VBS* includes a *humidifier*, use the minimum *humidifier* water level indicated in the *instructions for use*.

2) Use the test conditions for the first applicable column available on the *ventilator* (selected by intended *tidal volume* range) in Table 201.106.



Key

1	*ventilator* under test	5	data acquisition system
2	pressure sensor	6	resistance
3	flow sensor	7	test lung
4	oxygen sensor		

Figure 201.102 — Oxygen concentration change test setup

Table 201.106 — Test conditions for oxygen concentration change tests

Adjustable parameter	Test condition		
	For a *ventilator* intended to provide *tidal volume*		
	$V_T \geq$ 300 ml	300 ml $\geq V_T \geq$ 50 ml	$V_T \leq$ 50 ml
Tidal volume, V_T[a]	500 ml	150 ml	30 ml
Set rate	10 *breaths*/min	20 *breaths*/min	30 *breaths*/min
I:E ratio	1:2	1:2	1:2
Resistance, R[b][39][52][55]	5 hPa·(l/s)$^{-1}$ ± 10 %	20 hPa·(l/s)$^{-1}$ ± 10 %	50 hPa·(l/s)$^{-1}$ ± 10 %

[a] V_T is determined by using the settings of the *ventilator*.

[b] The accuracy for R applies over the ranges of the measured parameters.

3) Ventilate the test lung with a set oxygen concentration of 21 %.

4) Wait until equilibrium is reached in the inspired oxygen concentration at the *patient-connection port*.

5) Change the set oxygen concentration to the maximum delivered oxygen concentration that the *ventilator* permits.

6) Measure the time delay between setting the new concentration and achieving 90 % of the final oxygen concentration during inspiration at the *patient-connection port*. If the sensor is located inside the test lung, care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration. If the sensor is located in the tubing system, care should be taken to ensure that the measuring device has a sufficiently fast response to permit determination of the flow-weighted average concentration during the *inflation phase*.

7) Ensure that the measured time delay is less than or equal to that indicated in the *instructions for use*.

8) Repeat 3) to 7) for each applicable column (selected by intended *tidal volume* range) in Table 201.106.

9) If the *ventilator* is provided with bias flow during the *expiratory phase*, repeat 3) to 8) at the minimum *bias flow* setting available on the *ventilator*.

10) If the *ventilator* is provided with continuous flow throughout the *respiratory cycle*, repeat 3) to 8) at the minimum continuous flowrate setting available on the *ventilator*.

201.12.4 Protection against hazardous output

201.12.4.4 Incorrect output

Amendment (replace the compliance check with):

aa) Any pressure setting change and its relation to any other pressure settings shall be displayed while the setting is performed.

bb) Any setting that affects the *I:E ratio* or *inspiratory time* shall be displayed with the *I:E ratio* and *inspiratory time* while the setting is performed.

cc) The *ventilator* shall provide the *responsible organization* a means to allow the supervising clinician or the *healthcare professional operator* to have direct access to the *ventilation* settings and *alarm limits* (see 201.107).

dd) The *ventilator* shall provide the *responsible organization* or the supervising clinician or the *healthcare professional operator* a means to restrict the *lay operator* from adjusting the *ventilation* settings and *alarm settings* (see 201.107).

EXAMPLE Settings needing protection include *set rate*, *I:E ratio*, *inspiratory time*, adjustable pressure limitation, high inspiratory pressure *alarm limit*, and *inflation-type*.

Check conformity by functional testing.

Additional subclauses:

201.12.4.101 Oxygen monitor

a) If provided with a control for the setting of the inspiratory oxygen concentration, the *ventilator* shall either

1) be equipped with oxygen *monitoring equipment* for the measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the *patient-connection port)* that is integral to the *ventilator*, or

2) the *instructions for use* shall contain a statement to the effect that the *ventilator* is to be equipped with oxygen *monitoring equipment* for measurement of the inspiratory oxygen concentration (e.g. in the inspiratory limb or at the *patient-connection port*) before being put into service.

b) Integrated oxygen *monitoring equipment* shall conform with the following subclauses of ISO 80601-2-55:2018:

1) 201.7.4.3;

2) 201.7.9.2.9.101 k);

3) 201.12.1.101;

i) During the period of oxygen *monitoring equipment* calibration/zeroing according to ISO 80601-2-55:2018, 201.12.4.101.4.1 c), the display of *ventilation* parameters not derived from the oxygen *monitoring equipment* shall not be invalidated.

4) 201.12.1.102;

5) 201.12.1.103; and

6) 208.6.1.2.

c) Where the oxygen *monitoring equipment* is not an integral part of the *ventilator*, the *instructions for use* shall include information on where to connect the oxygen *monitoring equipment.*

d) The oxygen *monitoring equipment* shall, in addition, be equipped with an *alarm system* that detects a high oxygen level *alarm condition*.

e) The high oxygen level *alarm condition:*

1) shall be at least *medium priority;* unless

2) an *intelligent alarm system*, based on additional information, determines that the high oxygen level *alarm condition* is suppressed or its priority is changed

NOTE A low oxygen level *alarm condition* is required by ISO 80601-2-55.

Check conformity by application of the tests of ISO 80601-2-55:2018 and, if appropriate, inspection of the *instructions for use*.

201.12.4.102 Measurement of *airway pressure*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) The *ventilator* shall be equipped with *monitoring equipment* to indicate the *airway pressure*.

b) The site of actual measurement

1) may be anywhere in the *ventilator breathing system*, but

2) the indicated value shall be referenced to the *patient-connection port*.

c) Under steady-state conditions, the indicated *airway pressure* shall be accurate to within ± (2 hPa + 4 % of the actual reading) (± (2 cmH_2O + 4 % of the actual reading)).

d) The *airway pressure monitoring equipment* shall be equipped with an *alarm system* that detects at least a *medium priority alarm condition* to indicate when the low-*airway pressure alarm limit* is reached.

1) The *airway pressure monitoring equipment* may be equipped with an *alarm system* that starts with a *low priority alarm condition* to indicate when the *airway pressure* reaches the *alarm limit* and, if this state continues, escalates to a *medium priority alarm condition*.

e) The *airway pressure alarm limit* may be:

1) pre-adjusted;

2) *responsible organization*-configurable;

NOTE 2 There is guidance or rationale for this list item contained in Clause AA.2.

3) *operator*-adjustable;

4) *ventilator*-adjustable; or

5) a combination of *operator*-adjustable and *ventilator*-adjustable.

f) If the *alarm limit* is adjustable by the *ventilator*, a summary description of the algorithm that determines the *alarm limit* value shall be disclosed in the *instructions for use*.

NOTE 3 Depending on the type of *ventilation-mode* being used, there can be more than one active *alarm limit*.

Check conformity by functional testing.

201.12.4.103 Measurement of expired volume and low-volume *alarm conditions*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) A *ventilator* intended to provide a *tidal volume* greater than 50 ml shall be equipped with either:

1) *monitoring equipment* for indicating the volume expired through the *patient-connection port*; or

2) expiratory end-tidal CO_2 *monitoring equipment* (see 201.12.1.104).

b) *Monitoring equipment* for indicating the expired volume shall include an *alarm system* that detects a *technical alarm condition* to indicate when conditions in the *VBS* reach the *alarm limit* for high leakage (201.12.4.111).

c) The indication of the value of the expired volume *monitoring equipment* and associated *alarm conditions* may be disabled when the *tidal volume monitoring equipment* is in use.

d) The accuracy of expired volume *monitoring equipment* shall be disclosed in the *instructions for use*.

1) The *monitoring equipment* for indicating the volume expired through the *patient-connection port* may be provided by an option.

e) The expired volume *monitoring equipment* shall be equipped with an *alarm system* that detects at least *medium priority alarm conditions* to indicate when:

1) the low-expired volume *alarm limit* is reached; and

2) the high-expired volume *alarm limit* is reached.

f) The expired volume *monitoring equipment* may be equipped with an *alarm system* that:

1) starts with *low priority alarm conditions* to indicate when the expired volume reaches either *alarm limit* and,

2) if this state continues, escalates to *medium priority alarm conditions*.

g) The expired volume *alarm limits* may be:

1) pre-adjusted,

2) *responsible organization*-configurable,

NOTE 2 There is guidance or rationale for this list item contained in Clause AA.2.

3) *operator*-adjustable,

4) *ventilator*-adjustable, or

5) a combination of *operator*-adjustable and *ventilator*-adjustable.

h) If the *alarm limits* are adjustable by the *ventilator*, a summary description of the algorithm that determines the *alarm limit* values shall be disclosed in the *instructions for use*.

NOTE 3 Depending on the type of *ventilation-mode* being used, there can be more than one active *alarm limit*.

i) Check conformity by functional testing using the test conditions described in Table 201.104 and Table 201.105 and inspection of the *instructions for use*.

1) Select and set up the worst-case *VBS* configuration indicated in the *instructions for use*.

EXAMPLE Minimum and maximum *VBS* compliance.

2) For testing with a *humidifier*, where the measurement site is not proximal to the *patient-connection port*, perform the tests at the minimum and maximum water levels (two sets of tests for a *humidifier*).

201.12.4.104 Expiratory end-tidal CO_2 *monitoring equipment*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) Notwithstanding the requirements of 201.12.4.103 as an alternative to 201.12.4.103, a *ventilator* may be equipped with either:

1) CO_2 *monitoring equipment* for the measurement of expiratory carbon dioxide concentration (e.g. in the expiratory limb or at the *patient-connection port)* that is integral to the *ventilator*, or

2) a *functional connection* to CO_2 *monitoring equipment* that permits the *ventilator* to determine of when the CO_2 *monitoring equipment* is in use.

b) Integrated CO_2 *monitoring equipment* shall conform with the following subclauses of ISO 80601-2-55:2018:

1) 201.7.4.3;

2) 201.7.9.2.9.101 k);

3) 201.12.1.101;

i) During the period of CO_2 *monitoring equipment* calibration/zeroing according to ISO 80601-2-55:2018, 201.12.4.101.4.1 c), the display of *ventilation* parameters not derived from the CO_2 *monitoring equipment* shall not be invalidated.

4) 201.12.1.102;

5) 201.12.1.103; and

6) for expired CO_2 concentration, 208.6.1.2.

c) Where the CO_2 *monitoring equipment* is not an integral part of the *ventilator*, the *instructions for use* shall include the following:

1) statement to the effect that the *ventilator* is to be provided with CO_2 *monitoring equipment* that complies with ISO 80601-2-55:2018 before being put into service;

2) information on where to connect the CO_2 *monitoring equipment*.

Check conformity by inspection.

201.12.4.105 *Maximum limited pressure protection device*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

A *protection device* shall be provided to prevent the *airway pressure* from exceeding for more than 200 ms the lower of:

a) 20 hPa (20 cmH_2O) more than the high *airway pressure alarm limit*; or

b) 90 hPa (90 cmH_2O).

NOTE 2 This requirement applies in both *normal condition* and *single fault condition*. See 201.3.263.

NOTE 3 See also 201.12.4.106 and 201.12.4.112.

Check conformity by functional testing.

201.12.4.106 High-*airway pressure alarm condition*

a) The *ventilator* shall be equipped with *monitoring equipment* with an *alarm system* to indicate when the high-pressure limit for *airway pressure* is reached during the entire *respiratory cycle*.

b) The high-*airway pressure alarm condition* shall be:

1) *high priority;* or

2) *medium priority* and escalate to *high priority* if the high-*airway pressure alarm condition* exists for longer than ten consecutive *inflations* or 30 s, whichever is less.

3) The priority may escalate sooner than ten consecutive *inflations* or 30 s.

c) The high *airway pressure alarm limit* may be:

1) independently adjustable;

2) connected to an adjustable pressure limitation; or

3) related to the set pressure of the *ventilator*.

d) If the *alarm limit* is independently adjustable, it shall not be possible to set the high-*airway pressure alarm limit* to a value:

1) less than that of the adjustable pressure limitation; and

2) greater than the *maximum limited pressure*.

e) Means shall be provided to require the *operator* to perform a deliberate sequence of actions to confirm the setting of the high *airway pressure alarm limit* to values exceeding the lower of:

1) 20 hPa (20 cmH_2O) more than the *operator*-set pressure; or

NOTE 1 An example of the maximum set pressure is the sum of the set *BAP* and the set *Δ inspiratory pressure*.

NOTE 2 An example for a bi-level positive *airway pressure ventilation-mode*, is the sum of the set BAP_H and the set Δ_H *inspiratory pressure*. See ISO 19223:2019, Figure C.33.

NOTE 3 The *operator*-set pressure does not apply when by design the *ventilator* adjusts the *airway pressure* on a breath-by-breath basis.

2) 60 hPa (60 cmH_2O).

f) *Patient*-generated transient pressure increases less than 200 ms in duration should not cause the high *airway pressure alarm condition*.

EXAMPLE A transient pressure increase caused by the *patient* coughing.

g) The high *airway pressure alarm condition delay* shall not exceed 200 ms and the *ventilator* shall:

1) act to attempt to cause the pressure to start to decline within that duration; and

2) act to prevent the pressure from continuing to rise.

h) In *normal condition*, whenever the high-*airway pressure alarm condition* occurs, the *ventilator* shall reduce the *airway pressure* to the set *BAP* level within the lesser of:

1) one *respiratory cycle*; or

2) 5 s.

i) During *single fault condition*, the *ventilator* shall reduce the *airway pressure* to the set *BAP* level or below within no more 30 s.

j) The maximum *alarm signal generation delay* of the high-*airway pressure alarm condition* shall not exceed the lesser of:

1) three *respiratory cycles*; or

2) 15 s.

Check conformity by functional testing.

201.12.4.107 Obstruction *alarm condition*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) The *ventilator* shall be equipped with *monitoring equipment* with an *alarm system* that detects a *technical alarm condition* to indicate when conditions in the *VBS* reach the *alarm limit* for obstruction.

EXAMPLE *Alarm condition* to warn of the following:
— obstructed inspiratory breathing tube or expiratory *gas pathway*;
— blocked exhalation valve;
— blocked expiratory *breathing system filter*.

b) The obstruction *technical alarm condition*:

1) shall be *high priority*, unless

2) an *intelligent alarm system*, based on additional information, determines that the obstruction *technical alarm condition:*

i) is suppressed; or

ii) its priority is changed.

c) The maximum *alarm condition delay* shall be no more than the greater of:

1) two breath cycles; or

2) 5 s.

d) Whenever the obstruction *alarm condition* occurs, the *ventilator* shall, within no more than one breath cycle, reduce the *airway pressure* to either:

1) atmospheric pressure; or

2) the set *BAP* level.

e) The *ventilator* should be equipped with a *protection device* to allow spontaneous breathing when obstruction occurs.

f) If equipped with the *protection device*, the pressure drop measured at the *patient-connection port*, with all recommended *accessories* in place, shall not exceed 6,0 hPa (6,0 cmH_2O) at a flowrate of:

1) 30 l/min for a *ventilator* intended to provide a *tidal volume*, $V_T \geq 300$ ml;

2) 15 l/min for a *ventilator* intended to provide a *tidal volume*, 300 ml $\geq V_T \geq$ 50 ml;

3) 2,5 l/min for a *ventilator* intended to provide a *tidal volume*, $V_T \leq 50$ ml.

g) The *accompanying document* shall describe:

1) the means by which the obstruction *alarm condition* is determined; and

2) a means to test the obstruction *alarm condition*.

Check conformity by functional testing with each *VBS* indicated in the *instructions for use*, according to the test method described in the *accompanying document*.

201.12.4.108 Partial-occlusion *alarm condition*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) The *ventilator* should be equipped with *monitoring equipment* with an *alarm system* that detects a *technical alarm condition* to indicate when the expiratory *gas pathway* is partially occluded.

b) A summary description of the means by which the expiratory-gas-pathway-partial-occlusion *alarm condition* is determined shall be described in the *accompanying document*, if provided.

Check conformity by functional testing with each *VBS* indicated in the *instructions for use*, according to the test method described in the *accompanying document*.

201.12.4.109 Hypoventilation *alarm condition*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) The *ventilator* shall be equipped with *monitoring equipment* with an *alarm system* that detects an *alarm condition* to indicate hypoventilation.

b) The hypoventilation *alarm condition* shall include the detection of a lack of connection or disruption of the gas delivery to the *airway device* from the *ventilator.*

EXAMPLE 1 A lack of connection of the *breathing system* to the *gas output port.*

EXAMPLE 2 The incorrect configuration of the *breathing system*.

EXAMPLE 3 The inadvertent disconnection of *breathing system* components.

EXAMPLE 4 A lack of connection between the *patient-connection port* and *airway device*.

NOTE 2 The hypoventilation *alarm condition* can be determined, *inter alia*, by the measurement of the variations of *airway pressure* (201.12.4.102), expiratory volume (201.12.4.103), *tidal volume* (201.12.1.103), or CO_2 (201.12.4.104), low respiratory breathing rate or by an *intelligent alarm system* using one or more variables.

Check conformity by functional testing.

201.12.4.110 Continuing positive-pressure *alarm condition*

a) The *ventilator* shall be equipped with *monitoring equipment* with an *alarm system* that detects an *alarm condition* to indicate an unintended continuing positive pressure lasting for more than 17 s.

b) The continuing positive pressure *alarm condition* shall be at least *medium priority*.

c) The *technical description* shall disclose a summary of the algorithm used to determine the continuing positive-pressure *alarm condition.*

Check conformity by functional testing.

201.12.4.111 High leakage *alarm condition*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) The *ventilator* shall be equipped with an *alarm system* that detects a *technical alarm condition* to indicate when conditions in the *VBS* reach the *alarm limit* for high leakage.

b) The high leakage *technical alarm condition*

1) shall be at least *medium priority,* unless

2) an *intelligent alarm system*, based on additional information, determines that the high leakage *technical alarm condition:*

i) is suppressed; or

ii) its priority is changed.

c) The high leakage *technical alarm condition* may be disabled when the *tidal volume monitoring equipment* is in use.

Check conformity by functional testing.

201.12.4.112 Protection against inadvertent setting of high *airway pressure*

Means shall be provided to require the *operator* to perform a deliberate sequence of actions to confirm any *airway pressure* settings exceeding 60 hPa (60 cmH_2O). See also 201.12.4.105 a) and 206 b) 4).

Check conformity by functional testing.

201.12.101 Protection against accidental adjustments

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) Means of protection against accidental adjustment of controls that can create a *hazardous situation*, including against accidently turning the *ventilator* off, shall be provided.

b) Turning off the *ventilation* shall require at least a sequence of two very deliberate actions.

NOTE 2 This can be accomplished by means of hardware or software or a combination of both.

NOTE 3 This can be accomplished by two dedicated confirmation actions.

c) It shall be possible to set all *ventilator* parameters prior to starting any *ventilation-mode*.

d) The *usability* of these means of protection shall be evaluated in the *usability engineering process*.

NOTE 4 The requirements for the *usability engineering process* are found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 12.2 and IEC 60601–1-6:2010+AMD1:2013+AMD2:2020.

Check conformity by functional testing and inspection of *usability engineering file*.

201.13 *Hazardous situations* and fault conditions

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 13 applies, except as follows.

Additional subclauses:

201.13.2.101 Additional specific *single fault conditions*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

A *ventilator* shall be so constructed that the following *single fault conditions* shall not cause an unacceptable *risk*:

a) a disconnection or blockage of the gas delivery to the *ventilator*;

b) a disruption of the gas delivery to the *patient-connection port* from the *ventilator;*

c) when present, disconnection or blockage of the gas flow pathway from the *patient-connection port* to the *exhaust port;*

d) failure to install, removal of or failure of an *operator*-detachable *breathing system filter; and*

e) interruption of a *functional connection* between parts of the *ventilator* or *ME system*.

EXAMPLE 1 Loss of communication between the *ventilator* and its remote (wired or wireless) control or monitoring module.

EXAMPLE 2 Loss of communication between the *ventilator* and its *distributed alarm system*.

Check conformity by functional testing and inspection of *risk management file*.

201.13.101 Failure of one gas supply to a *ventilator*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) For a *ventilator* with multiple high-pressure gas supplies, following the failure of one external gas supply, the *ventilator* equipped with a means to deliver inspired oxygen concentrations greater than ambient shall maintain *basic safety* and *essential performance.*

b) If the *ventilator* is provided with a control for the setting of the inspiratory oxygen concentration, the *ventilator* shall be equipped with an *alarm system* that detects a *technical alarm condition* to indicate this gas supply failure.

c) The gas supply failure *technical alarm condition:*

1) shall be at least *low priority;* unless

2) an *intelligent alarm system*, based on additional information, determines that the gas supply failure *technical alarm condition* is suppressed.

NOTE For the purpose of this document, the failure of the blower is not considered as the failure of a gas supply.

Check conformity by functional testing.

201.13.102 Independence of *ventilation* control function and related *risk control* measures

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) A *single fault condition* shall not cause the simultaneous failure of:

1) a *ventilation*-control function; and

2) the corresponding *protection device*.

b) A *single fault condition* shall not cause either of the following to fail in such a way that the loss of the *ventilation*-control function is not detected:

1) a *ventilation*-control function and the corresponding *monitoring equipment*;

2) a *ventilation*-control function and the corresponding *alarm system*.

Check conformity by inspection and functional testing.

201.13.2.103 Failure of *functional connection* to a *ventilator* control or monitoring means

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) Following the failure of a *functional connection* to a *ventilator* control or monitoring means, the *ventilator* shall continue to ventilate the *patient*.

b) The *ventilator* shall be equipped with an *alarm system* that detects a *technical alarm condition* to indicate this communication failure.

c) The communication failure *technical alarm condition:*

1) shall be at least *medium priority;* unless

2) an *intelligent alarm system*, based on additional information, determines that the communication failure *technical alarm condition:*

i) is suppressed; or

ii) the priority is changed.

Check conformity by functional testing.

201.14 Programmable electrical medical systems (PEMS)

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 14 applies, except as follows.

201.14.1 General

Amendment (add prior to the compliance check):

aa) The *programmable electronic subsystems* (*PESS*) of a *ventilator* shall be developed with a design *process* conforming with:

1) IEC 62304:2006+AMD1:2015; and

2) IEC 81001-5-1:2021.

bb) The *ventilation* control *software items* of the *ventilator PESS* without an independent *risk control* measure external to the *PESS* shall be considered as software safety Class C.

1) Two independent *PESS* systems may be used to fulfil this requirement.

201.14.101 *Cybersecurity* capabilities

a) A *ventilator* should contribute to safe operation related to *cybersecurity*.

b) *Risk control* measures as specified in IEC/TR 60601-4-5:2021 Clauses 4 to 7 should be implemented as appropriate with following specific additions to IEC/TR 60601-4-5:2021, 4.6.3.

1) *Essential function*: After disconnection of all data interfaces to *IT-network* connections possibly subject to *attack* (via physical or logical disconnection), if necessary, after restarting the *ventilator* once, all clinical functions except of the affected remote functionality should be in place and operate as intended.

2) *Firecall* functions: If authentication for *operators* to *operator*-accessible settings is in place also for the user interface, a *firecall* function should be able to overrule that *operator* authentication combined with a log entry protected against modifications by the *operator* (i.e. *responsible organization* log).

3) Target *security level* SL-T: For user interfaces and for remote setting of clinical functions, the expected *security level* of SL-T, as specified in IEC/TR 60601-4-5:2021, is 1 or better. The expected *security level* of SL-T, as specified in IEC/TR 60601-4-5:2021, is 2 or better for secure updates or restorage of software, remotely or locally.

201.15 Construction of *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 15 applies, except as follows:

Additional subclauses:

201.15.101 Mode of operation

A *ventilator* shall be suitable for *continuous operation*.

Check conformity by inspection.

201.15.102 Delivered oxygen concentration

a) A *ventilator* shall be capable of delivering gas with an oxygen concentration of at least 25% at the *patient-connection port*.

1) The *instructions for use* shall disclose the *rated* range of delivered oxygen concentration.

b) The *rated* delivered oxygen concentration shall include the effects of:

1) the range of the *rated* input oxygen concentration;

2) the available flow from the oxygen source; and

3) the delivered flowrate to the *patient-connection port*.

Check conformity by functional testing.

201.15.103 *Accessory* self-check

a) A *ventilator* shall be equipped with means that allow the determination of whether or not the *VBS* resistance and compliance characteristics fall outside the values necessary to maintain normal operation.

NOTE Additional requirements are also found in 201.7.9.2.8.101.

b) This means might require *operator* action.

Check conformity by functional testing.

201.15.104 Integrated monitoring *VBS*

A *ventilator* should be designed in such a way to allow the use while in use of:

a) an integrated *VBS*, which allows the continuous monitoring of expired volume (201.12.4.103); or

b) the expiratory end-tidal CO_2 monitoring (201.12.4.104).

EXAMPLE A *ventilator* designed for use of a coaxial *breathing system* or a single limb *breathing system* that includes or provides connect ability to expiratory expired volume or expiratory end-tidal CO_2 in the close vicinity of the *patient-connection port*.

201.16 ME systems

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 16 applies, except as follows.

Additional subclause:

201.16.1.101 Additional general requirements for *ME systems*

Accessories connected to the *VBS* shall be considered to:

a) be part of the *ventilator;* or

b) form an *ME system* with the *ventilator*.

For *accessories* as part of the *ventilator*, check conformity in combination with the *ventilator*.

The testing need not to be repeated for each combination for a family of *accessories* with a family of *ventilators*. See 201.5 for worst case combinations.

For *accessories* forming an *ME system* with the *ventilator*, apply the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020, 16.1. Check conformity by application of the relevant tests of IEC 60601-1:2005+AMD1:2012+AMD2:2020, 16.1, and by application of the relevant tests.

201.16.2 *Accompanying documents* of an *ME system*

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

Amendment (add after list element c)):

100) if applicable, a description of the *use scenarios* and ranges of *ventilation* settings over which elevated temperature of the gas at the *ventilator gas output port* can lead to the failure of a respiratory gas *humidifier* to function according to its specification.

EXAMPLE 100 A blower-based *ventilator* operating with *ventilator* settings that result in the delivered breathing gas temperature exceeding 27 °C can cause the *humidifier* to reduce humidity output below the lower limit allowed by ISO 80601-2-74.

201.17 Electromagnetic compatibility of *ME equipment* and *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 17 applies.

Additional subclauses:

201.101 Gas connections

201.101.1 Connection to an inlet

201.101.1.1 *Low-pressure hose assembly*

If an *operator*-detachable *low-pressure hose assembly* is provided for connection between the *ventilator* and either a *medical gas pipeline system* or a pressure regulator, it shall conform with ISO 5359:2014+AMD1:2017.

Check conformity by application of the tests of ISO 5359:2014+AMD1:2017.

201.101.1.2 Filter

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

Each gas *inlet* should be provided with a filter.

NOTE 2 The need for particle filtration in oxygen-enriched environments including the proper choice of filter materials is discussed in ISO 15001:2010[13].

NOTE 3 Depending on the sensitivity against particles of the components used in the *gas pathways* (e.g. flow sensors) to particles, filtration of smaller particles can be needed.

201.101.2 *VBS connectors*

201.101.2.1 General

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) *Operator*-detachable *VBS* connections through which the main flow of gas to or from the *patient* passes in *normal condition*, excluding the *patient-connection port*

1) shall be

i) a 15 mm *connector* conforming with ISO 5356-1:2015;

ii) a 22 mm *connector* conforming with ISO 5356-1:2015; or

iii) for a *ventilator* only intended for *tidal volumes* of ≤300 ml, a 11,5 mm *connector* conforming with ISO 5356-1:2015.

2) may be a non-conical *connector* that does not engage with a conical *connector* conforming with ISO 5356-1:2015.

Check conformity by application of the tests of ISO 5356-1:2015 and functional testing.

201.101.2.2 Other named ports

201.101.2.2.1 *Patient-connection port*

The *patient-connection port* shall be one of the following:

a) a 15 mm conical socket *connector* conforming with ISO 5356-1:2015;

b) a 22 mm conical cone *connector* conforming with ISO 5356-1:2015; or

c) coaxial 15 mm/22 mm conical *connector* conforming with ISO 5356-1:2015.

Check conformity by application of the tests of ISO 5356-1:2015.

201.101.2.2.2 *Gas output port* and *gas return port*

a) The *gas output port* and the *gas return port* shall be one of the following

1) 22 mm conical cone *connector* conforming with ISO 5356-1:2015.

2) 15 mm conical cone *connector* conforming with ISO 5356-1:2015.

3) coaxial 15 mm/22 mm conical *connector* conforming with ISO 5356-1:2015.

4) a non-conical *connector* that does not engage with a conical *connector* conforming with ISO 5356-1:2015.

b) Notwithstanding this requirement, a *ventilator* only intended for *tidal volumes* of ≤300 ml, may be equipped with a *gas output port* or a *gas return port* using a 11,5 mm conical cone *connector* conforming with ISO 5356-1:2015.

Check conformity by application of the tests of ISO 5356-1:2015.

201.101.2.2.3 *Manual ventilation port*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

The *ventilator* shall not be equipped with a *manual ventilation port*.

Check conformity by inspection.

201.101.2.2.4 *Flow-direction-sensitive components*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

Any *operator*-detachable *flow-direction-sensitive component* of the *VBS* shall be so designed that it cannot be fitted in such a way that it presents an unacceptable *risk* to the *patient*.

Check conformity by inspection of *operator*-detachable *flow-direction-sensitive components* and inspection of the *risk management file*.

201.101.2.2.5 *Gas pathway* connection port

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) If provided, the *gas pathway* connection port of a *ventilator*, *VBS* or *accessory* shall:

   1) be provided with a means to secure the *accessory* in position; and

   2) a means to secure closure after removal of the *accessory*.

NOTE 2 This port directly connects to the gas pathway and is used e.g. for measuring gas concentrations or for introduction of liquids.

NOTE 3 For the purposes of this document, the temperature probe port specified in ISO 80601-2-74 is not considered a *gas pathway* connection port.

b) The *gas pathway* connection port of a *ventilator*, *VBS* or *accessory* may conform with ISO 80369-7:2021.

c) A *gas pathway* connection port that conforms with ISO 80369-7:2021 shall:

   1) be *marked* with either:

      i) the *symbol* ISO 7000-1641 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.1, *symbol* 11); or

      ii) if the *marking* is the primary *risk control* measure, the *safety sign* ISO 7010-M002 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.2, s*afety sign* 10).

   2) include in its *instructions for use* a warning to the effect that "Warning: As this [insert name of medical device here] uses a Luer connector for other than intravascular or hypodermic access, there is a possibility that an inadvertent connection can occur between this [insert name of medical device here] and another medical device or accessory using a Luer connector, which can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonably foreseeable risks."

Check conformity by inspection and, if applicable, by application of the tests of ISO 80369-7:2021.

201.101.2.2.6 Monitoring probe port

If a port is provided for introduction of a monitoring probe, it shall

a) not be compatible with *connectors* specified in ISO 5356-1:2015;

b) be provided with a means to secure the probe in position; and

c) be provided with a means to secure closure after removal of the probe.

Check conformity by inspection and application of the tests of ISO 5356-1:2015.

201.101.2.2.7 Gas *exhaust port*

a) If a *connector* is provided for the gas *exhaust port*, it shall be a 30 mm *connector* conforming with ISO 5356-1:2015.

NOTE A 30-mm *connector* conforming with ISO 5356-1:2015 is suitable for connection to anaesthesia gas scavenging system (AGSS) that complies with ISO 80601-2-13:2022.

b) A *ventilator* shall be designed so that any provided gas *exhaust port* is not obstructed during use.

Check conformity by inspection and application of the tests of ISO 5356-1:2015.

201.101.2.2.8 Temperature sensor port

The *VBS* may be equipped with a temperature sensor port conforming with 201.101.8 of ISO 80601-2-74:2021.

201.102 Requirements for the *VBS* and *accessories*

201.102.1 General

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

All *ventilator breathing systems*, their parts, and *accessories* shall conform with the requirements of this document, whether they are produced by the *manufacturer* of the *ventilator* or by another entity ("third-party manufacturer" or healthcare provider).

Check conformity by the tests of this document.

201.102.2 Labelling

a) The *accompanying document* provided with each *VBS* or *accessory*, conforming with 201.102.1, shall include the *model or type reference* of at least one compatible *ventilator*.

b) Statements shall be included in the *accompanying document* of each *ventilator breathing system*, part, or *accessory* to the effect that:

   1) ventilator breathing systems, their parts, and accessories are validated for use with specific ventilators,

   2) incompatible parts can result in degraded performance; and

   3) the responsible organization is accountable for the compatibility of the ventilator and all of the parts and accessories used to connect to the patient before use.

Check conformity by inspection of the *accompanying document*.

201.102.3 Breathing sets

Breathing sets, other than heated breathing tubes, intended for use in the *VBS* shall conform with ISO 5367:2014, 5.3.4.

NOTE Heated breathing tubes are covered by ISO 80601-2-74.

Check conformity by application of the tests of ISO 5367:2014.

201.102.4 Water vapour management

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

201.102.4.1 Humidification system

Any *humidifier*, including heated breathing tubes, either incorporated into the *ventilator* or recommended for use with the *ventilator*, shall conform with ISO 80601-2-74:2021.

Check conformity by application of the tests of ISO 80601-2-74:2021.

201.102.4.2 *Heat and moisture exchanger (HME)*

Any *HME*, either incorporated into the *VBS* or recommended for use with the *VBS*, shall conform with:

a) ISO 9360-1:2000; or

b) ISO 9360-2:2001.

Check conformity by application of the tests of ISO 9360-1:2000 or ISO 9360-2:2001.

201.102.5 *Breathing system filters (BSF)*

Any *BSF*, either incorporated into the *ventilator* or recommended for use with the *ventilator*, shall conform with:

a) ISO 23328-1:2003; and

b) ISO 23328-2:2002.

Check conformity by application of the tests of ISO 23328-1:2003 and ISO 23328-2:2002.

201.102.6 *Ventilator breathing systems*

201.102.6.1 Leakage from the *operator*-detachable parts of the *VBS*

Unintended leakage from the *operator*-detachable parts of the *VBS* shall not exceed the following and at a continuous pressure of (60 ± 3) hPa ((60 ± 3) cmH_2O):

a) 70 ml/min if specified for a *ventilator* with an intended *tidal volume* ≥300 ml;

b) 40 ml/min if specified for a *ventilator* with an intended *tidal volume* between 50 ml and 300 ml; and

c) 30 ml/min if specified for a *ventilator* with an intended *tidal volume* ≤50 ml.

d) Check conformity by the following test.

1) Set up the *VBS* for the intended application as indicated in the *instructions for use*.

2) Seal all ports.

3) Connect a pressure-measuring device and introduce the air into the *VBS* until a pressure of 60 hPa (60 cmH_2O) is reached.

4) Adjust the flow of air to stabilize the pressure and record the leakage flow.

201.102.6.2 Non-invasive *ventilation*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

The *instructions for use* for a *ventilator* intended for non-invasive *ventilation* shall include a warning statement to the effect that the exhaled volume of the *patient* can differ from the indicated exhaled volume due to leaks around the *mask*.

Check conformity by inspection of the *instructions for use*.

201.103 Spontaneous breathing during loss of power supply

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) A *protection device* shall be provided to allow spontaneous breathing when normal *ventilation* is compromised as a result of the electrical or pneumatic supply power being outside the values necessary for normal operation.

b) Under these conditions, the inspiratory and expiratory pressure drop measured at the *patient-connection port* with all recommended *accessories* in place shall not exceed 6,0 hPa (6,0 cmH_2O) at a flowrate of:

1) 30 l/min for a *ventilator* intended to provide a *tidal volume*, $V_T \geq 300$ ml;

2) 15 l/min for a *ventilator* intended to provide a *tidal volume*, 300 ml $\geq V_T \geq 50$ ml; and

3) 2,5 l/min for a *ventilator* intended to provide a *tidal volume*, $V_T \leq 50$ ml.

NOTE 2 This requirement is intended to allow the *patient* to breathe spontaneously under compromised conditions.

Check conformity by functional testing and measurement of flow, pressure, and resistance at the *patient-connection port* with that combination of *accessories* indicated in the *instructions for use* that produces the greatest pressure drop.

201.104 Indication of duration of operation

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) The *ventilator* shall have means to indicate visually the cumulative hours of operation of the *ventilator, either:*

1) automatically; or

2) by *operator* action,

b) The *ventilator* should also have means by *operator* action to indicate visually:

1) the time since the last preventive maintenance; or

2) the time until the next recommended preventive maintenance.

Check conformity by inspection.

201.105 Functional connection

201.105.1 General

Basic safety and *essential performance* shall be maintained if connections to the *functional connection* of 201.105 of a *ventilator* are:

a) disrupted; or

b) if the equipment connected to those parts fails.

Check conformity by functional testing.

201.105.2 Connection to an electronic health record

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

A *ventilator* should be equipped with a *functional connection* that permits data transmission from the *ventilator* to an electronic health record.

201.105.3 Connection to a *distributed alarm system*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

A *ventilator* shall be equipped with a *functional connection* that permits connection to a *distributed alarm system*.

Check conformity by inspection.

201.105.4 Connection for remote control

A *ventilator* may be equipped with a *functional connection* for external control of the *ventilator*.

201.106 Display loops

201.106.1 Pressure-volume loops

a) If a *ventilator* is provided with the display of pressure-volume loops, the graph shall use the following:

   1) *tidal volume* on the vertical axis;

   2) *airway pressure* on the horizontal axis.

b) Positive values shall be on the top and the right of the display.

c) Increases in *tidal volume* shall be positive values.

d) The volume shall be reset to the origin at the beginning of each breath.

Check conformity by inspection.

201.106.2 Flow-volume loops

a) If a *ventilator* is provided with the display of flow-volume loops, the graph shall use the following:

   1) flowrate on the vertical axis;

   2) *tidal volume* on the horizontal axis.

b) Positive values shall be on the top and the right of the display.

c) Gas flow to the *patient* (inspiratory flow) and increases in *tidal volume* shall be positive values.

d) The volume shall be reset to the origin at the beginning of each breath.

e) The *ventilator* may be provided with an additional optional display configuration for the flow-volume loop where gas flow from the *patient* (expiratory flow) is represented as a positive value.

Check conformity by inspection.

201.107 *Ventilator* security

Means of restricting access to changing or to the storage of changes shall be described in the *technical description* (see 201.12.4.4).

EXAMPLE 1 Access controlled by a *tool*.

EXAMPLE 2 Access controlled by *responsible organization* password and a *technical description* that is separate from the *instructions for use*.

EXAMPLE 3 Access controlled by individual *operator* password.

NOTE 1 For a password to be considered secure, the owner of the password needs to be capable of changing the password.

EXAMPLE 4 Access controlled by voice recognition.

EXAMPLE 5 Access controlled by fingerprints.

NOTE 2 Multiple means of restriction can be needed (e.g. one for the *responsible organization* and one for each *operator)*.

Check conformity by inspection of the *technical description*.

201.108 Oxygen inlet port

a) An oxygen inlet *connector* of the *ventilator*, which is not intended for direct connection to the *medical gas pipeline system* (201.101.1) and is *operator*-accessible without the use of a *tool,* shall conform with ISO 80369-1:2018.

b) A *ventilator* with this inlet *connector* shall maintain *basic safety* and *essential performance* with oxygen supply systems up to 600 kPa, in *normal condition*.

NOTE It is expected that the R2 *connector* of ISO 80369-2 will meet this criterion.

Check conformity by functional testing and application of the tests of ISO 80369-1:2018.

202 Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014+AMD1:2020 *applies except as follows:*

202.4.3.1 Compliance criteria

Amendment (replace the second dash of 4.3.1 with):

NOTE 100 There is guidance or rationale for this subclause contained in Clause AA.2.

— the *ventilator* operated using the worst-case conditions and parameters of 201.12.1.102 or 201.12.1.103, selected by intended *tidal volume*, as appropriate. During this testing, set the volume and pressure *alarm condition alarm limits* to their least sensitive levels.

202.5.2.2.1 Requirements applicable to all *ME equipment* and *ME systems*

Amendment (add note to list element b)):

NOTE The requirements of this document are not considered deviations or allowances.

Addition:

202.8.1.101 Additional general requirements

a) The *ventilator* shall be tested according to the requirements for the *home healthcare environment*.

b) The following degradations, if associated with *basic safety* and *essential performance*, shall not be allowed:

1) component failures;

2) changes in programmable parameters or settings;

3) reset to default settings;

4) change of operating mode;

EXAMPLE Change of *inflation-type*, *ventilation-mode*, *set rate*, *I:E ratio*.

5) initiation of an unintended operation;

6) during the testing, the error of the:

i) *inspiratory volume* of individual *inflations* deviating by more than 35 % of the *inspiratory volume* measured prior to the test;

ii) *inspiratory volume* averaged over a one-minute interval deviating by more than 25 % of the *inspiratory volume* measured prior to the test;

III) One-minute averaged testing need not be performed if the volume of individual *inflations* does not deviate by more than 25 %.

iii) *PEEP* of individual *inflations* deviating by more than 5 hPa (5,0 cmH_2O) from the *PEEP* measured prior to the test; and

iv) if provided with a control for the setting of the inspiratory oxygen concentration, delivered FiO_2 averaged over a one-minute interval deviating by more than the deviation disclosed by the *manufacturer* in the *instructions for use*.

I) One-minute averaged testing need not be performed if the FiO_2 of individual *inflations* does not deviate by more than the deviation disclosed in the *instructions for use*.

c) The *ventilator* can exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the *instructions for use* during *immunity* testing) that does not affect *basic safety* or *essential performance*.

206 Usability

IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 applies except as follows.

Addition:

206.101 *Primary operating functions*

a) For a *ventilator*, the following shall be considered *primary operating functions*:

1) setting the *operator*-adjustable controls;

i) setting *alarm limits*;

ii) inactivating *alarm signals*;

iii) switching between different *ventilation-modes* and *inflation-types*;

iv) setting *ventilation* control parameters;

EXAMPLE 1 *Set rate*, *tidal volume*, *set BAP*, pressure support.

2) observing and identifying monitored *ventilation* parameters;

EXAMPLE 2 *Airway pressure* and expired volume.

3) observing and identifying:

i) the *alarm signals*; and

ii) the *alarm signal* inactivation states;

4) configuring the *VBS*, including;

EXAMPLE 3 *Humidifier*, nebulizer, water-trap, tubing, *breathing system filter*, *monitoring equipment*.

i) connection of the detachable parts of the *VBS* to the *ventilator;*

5) connecting or disconnecting the *patient-connection port* of the *VBS* to the *patient*-interface;

6) *processing* the *VBS* components;

7) starting the *ventilator* from power off;

8) turning off the *ventilator*;

9) performing a basic pre-use functional check of the *ventilator* including the *alarm system*;

10) identifying any limitation of the *ventilator's* ability to detect decannulation or extubation based on the intended *patient* profile and the *VBS* configuration;

11) switching between power sources;

12) testing power sources; and

13) connecting and disconnecting the *distributed alarm system*.

b) The following functions, if available, shall also be considered *primary operating functions*:

1) starting *ventilation* from standby;

2) activating standby;

3) setting of the adjustable high-pressure *alarm limit* to values exceeding 60 hPa (60 cmH_2O);

4) setting of the adjustable high-pressure *alarm limit* to values exceeding 20 hPa (20 cmH_2O) more than the maximum set *airway pressure*; and

5) setting of the *airway pressure* to values exceeding 60 hPa (60 cmH_2O).

c) The following actions associated with *ventilation* shall also be considered *primary operating functions*:

NOTE For the purposes of this document, the following functions are considered *primary operating functions* even though they are not performed on the *ventilator's operator interface*.

1) humidifying/conditioning gases delivered through the *VBS*;

2) adding medication to the gas flowing into the *patient*;

EXAMPLE 4 Nebulisation or injecting fluids into the ancillary port connection of the *VBS.*

3) suctioning the *patient's* airway; and

4) for a *transit operable ventilator*, positioning the *patient* and the *ventilator* on the wheelchair.

206.102 Training

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

In the application of the requirements in 5.6 and 5.8 of IEC 62366-1:2015, training shall be considered necessary for:

a) the *healthcare professional operator;*

b) the *lay operator*; and

c) the designee of the *responsible organization* (e.g. *service personnel* or *processing* personnel).

NOTE 2 Requirements for training are found in 5.6 and 5.8 of IEC 62366-1:2015.

Check conformity by inspection of the *accompanying document.*

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 applies except as follows.

Additional subclauses:

208.6.8.3.101 Additional requirements for global indefinite *alarm signal* inactivation states

A *ventilator* shall not be equipped with a means to initiate a global *alarm off* while connected to a *patient.*

Check conformity by functional testing.

208.6.8.4.101 Additional requirements for termination of *alarm signal* inactivation

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

The duration of *alarm paused*, *audio paused* or *acknowledged* for the *alarm conditions* required by this document shall not exceed 120 s without *operator* intervention.

NOTE 2 This permits an *operator* to deliberately extend the duration of *audio paused* by no more than 120 s following each direct action.

Check conformity by functional testing.

208.6.12.3.101 Additional requirements for *operator alarm system* logging

A *ventilator* shall be provided with an *operator* log with a capacity of at least 1 000 events in total.

Check conformity by inspection and functional testing.

208.6.12.3 *Responsible organization alarm system* logging

Replacement:

a) A *ventilator* shall be provided with a *responsible organization* log with a capacity of at least 1 000 events in total.

b) Viewing the *responsible organization alarm system* log shall be restricted to the *responsible organization* in accordance with IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.7.

c) The *responsible organization alarm system* log shall include all of the information contained in the *operator alarm system* log, if provided.

d) The *responsible organization alarm system* log shall contain:

   1) the *ventilator* settings; and

   2) each change of those settings.

   EXAMPLE 1 The name of the *ventilator* preset in use and any changes made to it.

e) The *responsible organization alarm system* log shall contain:

   1) the *alarm settings*; and

   2) each change of those settings.

   EXAMPLE 2 The name of the *alarm preset* in use and any changes made to it.

f) Means shall not be provided for the *operator* or *responsible organization* to edit or delete entries in the *responsible organization alarm system* log.

g) The *responsible organization alarm system* log shall be retained when the *alarm system* is powered down.

h) The *technical description* shall indicate what happens to the contents of the log after the *alarm system* has experienced a total loss of power (*supply mains* and *internal electrical power source*) for a finite duration.

i) The *technical description* shall indicate:

   1) the *responsible organization alarm system* log capacity;

   2) what happens to the contents of the *alarm system* log as it reaches capacity; and

      EXAMPLE 3 The *alarm system* discards the oldest data when the log becomes full.

   3) how to access and download the contents of the *responsible organization alarm system* log.

j) The *alarm system* should log *technical alarm conditions* for servicing and maintenance purposes. This log should not be resettable or editable by *operator* action.

k) The log may be provided either within the equipment or remotely through a communications interface.

Check conformity by inspection and functional testing.

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015+AMD1:2020 *applies except as follows:*

211.7.4.7 Additional requirements for *cleaning*, *disinfection* and *sterilization*

Amendment (add after 'intended use, ' in the first paragraph):

in either *normal condition* or *single fault condition*,

211.7.4.8 Additional requirements for maintenance

Amendment (add following the second list element):

100) Any known unacceptable *risk* associated with using the *ME equipment*, its parts or *accessories* for longer than the *expected service life* shall be disclosed in the *instructions for use.*

Additional subclauses:

211.8.4.101 Additional requirements for interruption of the power supply/*supply mains* to *ME equipment*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) Notwithstanding the requirements of IEC 60601-1-11:2015+AMD1:2020, 8.4, the *ventilator* shall be equipped with the following:

1) an *internal electrical power source* capable of powering the *ventilator* for at least 2 h when the *supply mains* falls outside the values necessary to maintain normal operation;

2) a means of determining the state of this *internal electrical power source.*

b) As the *internal electrical power source* depletes, but at least 15 min prior to the loss of all power, the *ventilator* shall be equipped with a means to detect an impending *internal electrical power source* failure *alarm condition*.

1) It shall be of at least *medium priority*.

2) The impending *internal electrical power source* failure *alarm condition* priority shall escalate to *high priority* at least 5 min prior to the depletion of the *internal electrical power source*.

3) There shall be at least 5 min between the beginnings of these two *alarm conditions*.

4) The *instructions for use* shall state the time between loss of all power and the generation of *alarm signals* for the impending *internal electrical power source* failure warning *alarm condition*.

NOTE 2 The *operator* needs sufficient time "prior to the loss of all power" to take action to ensure that alternative arrangements can be made to continue the life-supporting function of the *ventilator*.

c) The *instructions for use* shall disclose the following:

1) the operational time of the *ventilator* when powered from each power source under the following conditions:

i) an aged (see d) 1), fully charged power source;

ii) *tidal volume*, V_T = 800 ml or the largest *rated tidal volume*, whichever is smaller;

iii) *set rate* = 20 min^{-1};

iv) *I:E ratio* = 1:2;

v) resistance, *R* = 5 $hPa(l/s)^{-1}$ ± 10 %;

vi) compliance, *C* = 50 ml $(hPa)^{-1}$ ± 10 %;

2) how the alternative *supply mains* can be tested;

3) the behaviour of the *ventilator* after a switch-over to the *internal electrical power source* or alternative *supply mains*;

4) the behaviour of the *ventilator* while the *internal electrical power source* or alternative *supply mains* is recharging.

d) Check conformity by inspection of the *instructions for use*, functional testing and the *following test*.

1) Age a new *internal electrical power source* by operating the *ventilator* from the *internal electrical power source* using the worst-case intended *tidal volume* and *inflation-type* under the conditions of Table 201.102:

i) until the *high priority internal electrical power source* nears depletion *technical alarm condition* becomes active;

ii) recharge the *internal electrical power source* by connecting the *ventilator* to *supply mains*;

I) A dwell time may be inserted following recharging to permit the *ventilator* to reach thermal equilibrium.

iii) repeat i) and ii) 10 times; and

iv) for a *transit-operable ventilator*, repeat i) and ii) an additional 40 times.

v) Instead of using the *ventilator*, discharging and charging circuits may be used with an equivalent profile simulating worst-case conditions:

I) temperature of the *internal electrical power source* while in use;

II) over the discharging time; and

III) over the charging time.

2) Operate the *ventilator* using an intended *tidal volume* and *inflation-type* under the conditions of Table 201.102.

3) Confirm that the *medium priority alarm condition* occurs at least 10 min prior to the loss of ventilation.

4) Confirm that the *high priority alarm condition* occurs at least 5 min prior to the loss of ventilation.

5) Repeat 2) to 4) for each remaining range of intended *tidal volume*.

211.10.1.1 General requirements for mechanical strength

Amendment (add as the first paragraph):

a) The tests of IEC 60601-1-11:2015+AMD1:2020, Clause 10 and IEC 60601-1:2005+AMD1:2012+AMD2:2020, 15.3 shall be performed on the same test *ventilator*

after the *cleaning* and *disinfection procedures* of 201.11.6.6 of this document have been performed unless there are no *cleaning* and *disinfection procedures* specified in the *instructions for use*.

b) If more than one *procedure* is specified in the *instructions for use*, each *procedure* shall be so tested.

1) A separate *ventilator* may be used for each specified *procedure*.

Annexes of IEC 60601-1:2005+AMD1:2012+AMD2:2020, apply, except as follows.

Annex C
(informative)

Guide to marking and labelling requirements for ME equipment and ME systems

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Annex C applies, except as follows:

Addition:

201.C.1 *Marking* on the outside of *ME equipment*, *ME systems,* or their parts

Additional requirements for *marking* on the outside of a *ventilator*, its parts, and *accessories* are found in Table 201.C.101.

Table 201.C.101 — *Marking* on the outside of a *ventilator*, its parts or *accessories*

Description of *marking*	Subclause
Arrow indicating the direction of the flow for *flow-direction-sensitive components*, if applicable	201.7.2.101 a) 3)
For a *ventilator* intended for the magnetic resonance (MR) environment, MR safe, if applicable	201.7.2.101 a) 1) i)
For a *ventilator* intended for the magnetic resonance (MR) environment, MR conditional, if applicable	201.7.2.101 a) 1) ii)
For a *ventilator* not intended for the magnetic resonance (MR) environment, MR unsafe, if applicable	201.7.2.101 a) 2)
For *accessories* supplied separately, indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable	201.7.2.4.101 a) 2)
For *accessories* supplied separately, the requirements of 201.102.1	201.7.2.4.101 a) 1)
Gas name or chemical *symbol* for any gas-specific inputs and *outlets*, if applicable	201.7.2.101 b) 1) i)
Gas-specific colour coding for any gas-specific inputs and *outlets*, if applicable	201.7.2.101 b) 1) ii)
Legibility of controls or indicators	201.12.1 aa)
Mandatory action safety sign: follow *instructions for use*	201.7.2.3
The gas name or chemical *symbol* adjacent to the input *connector*	201.7.2.18 a)
The *rated* range of gas pressure adjacent to the input *connector*	201.7.2.18 b)
The *rated* range of oxygen concentration adjacent to the input *connector* of the oxygen gas input	201.7.2.18 c)
Trigger sensitivity control minimum and maximum settings self-evident, if applicable	201.7.4.2 aa)
Trigger sensitivity control not only numeric, if applicable	201.7.4.2 bb) 2)
Trigger sensitivity control uses lowest number to represent the setting for the least *patient* effort, if applicable	201.7.4.2 bb) 1)
Warning not to obstruct the *gas intake port*, if applicable	201.7.2.101 b) 2)

201.C.2 *Accompanying documents*, general

Additional requirements for general information to be included in the *accompanying documents* of a *ventilator* or its parts are found in Table 201.C.102.

Table 201.C.102 — *Accompanying documents*, general

Description of requirement	Subclause
Description of the means by which the obstruction *alarm condition* is determined	201.12.4.107 g) 1)
Description of the means by which the partial-occlusion *alarm condition* is determined, if provided	201.12.4.108 b)
Description of the means to test the obstruction *alarm condition*	201.12.4.107 g) 2)
Description of the *use scenarios* and ranges of *ventilation* settings over which elevated temperature of the gas at the *ventilator gas output port* can lead to the failure of a respiratory gas *humidifier* to function according to its specification, if applicable	201.16.2
For each *VBS* and *accessory*, the *model or type reference* of at least one compatible *ventilator*	201.102.2 a)
For each *VBS* part and *accessory*, a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b) 2)
For each *VBS* part and *accessory*, a statement to the effect that the responsible organization is accountable for the compatibility of the ventilator and all of the parts and accessories used to connect to the patient before use	201.102.2 b) 3)
For each *VBS* part and *accessory*, a statement to the effect that ventilator breathing systems, their parts, and accessories are validated for use with specific ventilators	201.102.2 b) 1)
Maximum time-weighted average input flow for each gas, if applicable	201.4.11.101.2 3) i)
Maximum transient input flow for each gas, if applicable	201.4.11.101.2 3) ii)
Units of measure for *airway pressure* capable of being in hPa	201.7.4.3 bb)
Units of measure for volumes, flows, and leakages expressed as *STPD* or *BTPS*, as appropriate	201.7.4.3 aa)
Warning that the *ventilator* is a high flow device, if applicable	201.4.11.101.2 3) iii)

201.C.3 *Accompanying documents, instructions for use*

Additional requirements for information to be included in the *instructions for use* of a *ventilator* or its parts are found in Table 201.C.103.

Table 201.C.103 — *Instructions for use*

Description of requirement	Subclause
Accuracy of expired volume *monitoring equipment*, if equipped	201.12.4.103 d)
Accuracy of the *tidal volume monitoring equipment*	201.12.1.105 b)
Alternative *supply mains*, maximum current required	201.11.8.101 b) 4)
Alternative *supply mains*, means of connection	201.11.8.101 b) 1)
Alternative *supply mains*, *nominal* voltage	201.11.8.101 b) 3)
Alternative *supply mains*, *rated* voltage range	201.11.8.101 b) 2)
Any adverse effect of any recommended *accessory* on the *basic safety* or *essential performance* of the *ventilator*, if applicable	201.7.9.2.14.101 b)

Description of requirement	Subclause
Any known unacceptable *risk* associated with using the *ME equipment*, its parts or *accessories* for longer than the *expected service life*	211.7.4.8 1)
A-weighted sound power level emitted by the *ventilator*	201.9.6.2.1.101 b) 2)
A-weighted sound pressure level emitted by the *ventilator*	201.9.6.2.1.101 a) 2)
Behaviour of the *ventilator* after a switchover to the *internal electrical power source* or alternative *supply mains*	211.8.4.101 c) 3)
Behaviour of the *ventilator* while the *internal electrical power source* or external reserve electrical power source is recharging	211.8.4.101 c) 4)
Description of periodic visual safety inspections that should be performed by the *operator*	201.7.9.2.13.101 a)
Description of the *internal electrical power source* care and maintenance *procedures*, including instructions for recharging or replacement, if applicable	201.7.9.2.13.101 b)
Disclosure of any restrictions on the placing of components within the *ventilator breathing system*, if applicable	201.7.9.2.14.101 a)
For a *ventilator* intended for non-invasive *ventilation*, a warning statement to the effect that the exhaled volume of the *patient* can differ from the measured exhaled volume due to leaks around the *mask*	201.102.6.2
For a *ventilator* that is not provided with a control for the setting of the inspiratory oxygen concentration, the length of time required for an increase of oxygen concentration in the *tidal volume*	201.7.9.2.9.101.2 d)
For a *ventilator* that is not provided with a control for the setting of the inspiratory oxygen concentration, indicate that when the oxygen source is from an oxygen concentrator, the time can be significantly longer	201.7.9.2.9.101.2 d) 2)
For *accessories* supplied separately where *marking* the *accessory* is not practicable, the requirements of 201.7.102.1	201.7.2.4.101 b)
For other *inflation*-types, the acceptance criteria for the performance	201.12.1.104 a) 2)
For other *inflation*-types, the performance at the *patient-connection port*	201.12.1.104 a) 1)
For the *lay operator* instructions, a description of a means to determine the operation time of the *internal electrical power source*	201.7.9.2.9.101.1 f)
For the *lay operator* instructions, a description of how the listed *alarm conditions* can be tested	201.7.9.2.9.101.1 d)
For the *lay operator* instructions, a description of how the listed *alarm conditions* can be tested, if provided	201.7.9.2.9.101.1 e)
For the *lay operator* instructions, a description of how to connect and test a *distributed alarm system*	201.7.9.2.9.101.1 g)
For the *lay operator* instructions, an explanation of the meaning of the IP classification	201.7.9.2.9.101.1 b)
For the *lay operator* instructions, an indication as to whether the *ventilator* is intended for non-invasive *ventilation*	201.7.9.2.9.101.1 c)
For the *lay operator* instructions, conditions under which the *ventilator* maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101.1 a)
For the *lay operator* instructions, method by which all of the *alarm signals*, including the *alarm signals* from *distributed alarm systems,* can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 3)

Description of requirement	Subclause
For the *lay operator* instructions, method by which all switchover to and operation from the *internal electrical power source* can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 2)
For the *lay operator* instructions, method by which the assembled breathing tubes and related *accessories* can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 1)
For the *lay operator* instructions, the specifications of any *accessories* or equipment required to perform the tests described in 201.7.9.2.8.101	201.7.9.2.8.101 c)
For the supervising clinician or the *healthcare professional operator instructions for use*, the information contained in the *instructions for use* for the *lay operator*	201.7.9.2.8.101 c)
For the supervising clinician or the *healthcare professional operator* instructions, method by which all functions and settings necessary for *normal use* can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 d)
For the supervising clinician or the *healthcare professional operator* instructions, the working principle of each of the *ventilator's ventilation-modes* including waveforms	201.7.9.2.9.101.2 a) 1)
For the supervising clinician or the *healthcare professional operator* instructions, the methods for controlling the cycling	201.7.9.2.9.101.2 a) 2)
For the supervising clinician or the *healthcare professional operator* instructions, the parameter settings	201.7.9.2.9.101.2 a) 3)
For the supervising clinician or the *healthcare professional operator* instructions, the range of parameter settings	201.7.9.2.9.101.2 a) 4)
For the supervising clinician or the *healthcare professional operator* instructions, any limitation of parameter settings	201.7.9.2.9.101.2 a) 5)
For the supervising clinician or the *healthcare professional operator* instructions, a description of how the listed *alarm conditions* can be tested	201.7.9.2.9.101.2 a) 6)
For the supervising clinician or the *healthcare professional operator* instructions, a statement as to whether any portion of the gas supplied to a *high-pressure inlet* is supplied to the *patient*, if applicable	201.7.9.2.9.101.2 c) 2)
For the supervising clinician or the *healthcare professional operator* instructions, the *rated* range of inspiratory *gas pathway* resistances of the assembled *operator*-detachable parts of the *VBS*, over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101.2 b) 1)
For the supervising clinician or the *healthcare professional operator* instructions, the *rated* range of expiratory *gas pathway* resistances of the assembled *operator*-detachable parts of the *VBS*, over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101.2 b) 2)
For the supervising clinician or the *healthcare professional operator* instructions, the *rated* range of compliance of the assembled *operator*-detachable parts of the *VBS*, over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101.2 b) 3)
For the supervising clinician or the *healthcare professional operator* instructions, the essential technical characteristics of each recommended *breathing system filter*, if applicable	201.7.9.2.9.101.2 c) 1)
Information on where to connect CO_2 *monitoring equipment*, if not so equipped, if applicable	201.12.4.104 c) 2)

Description of requirement	Subclause
Information on where to connect O_2 *monitoring equipment*, unless such equipment is an integral part of the *ventilator*	201.12.4.101 c)
Intended position of the *operator*	201.7.9.2.1
Intended range of *tidal volume*	201.7.9.2.1.101 d) 1)
Length of time between the loss of power and impending *internal electrical power source* failure warning *alarm condition*	211.8.4.101 b) 4)
length of time required for ventilator to achieve 90 % of maximum achievable oxygen concentration	201.12.1.106 a)
Maximum error of the *airway pressure* at the end of the *inflation phase* in relation to the set value for a *pressure-control* breath in *normal condition*	201.12.1.103 b) 1)
Maximum error of the *airway pressure* at the end of the *inflation phase* in relation to the set value for a *pressure-control* breath in *normal condition* under leak condition	201.12.1.103 b) 2)
Maximum error of the inspiratory oxygen concentration (FiO_2) at the *patient-connection port* in relation to the set value for a *volume-control* breath in *normal condition*, if provided	201.12.1.102 b) 3)
Maximum error of the inspiratory oxygen concentration (FiO_2) at the *patient-connection port* in relation to the set value for a *pressure-control* breath in *normal condition*, if provided	201.12.1.103 b) 4)
Maximum error of the *PEEP* in relation to the set *BAP* value for a *volume-control* breath in *normal condition*	201.12.1.102 b) 2)
Maximum error of the *PEEP* in relation to the set *BAP* value for a *pressure-control* breath in *normal condition*	201.12.1.103 b) 3)
Maximum error of the *tidal volume* in relation to the set value for a *volume-control* breath in *normal condition*	201.12.1.102 b) 1)
Means by which the alternative *supply mains* can be tested	211.8.4.101 c) 2)
Operational time of the power sources when fully charged	211.8.4.101 c) 1)
Processing instructions for the *ventilator* and its *accessories*	201.11.6.6 cc)
Processing instructions for the *ventilator enclosure*	201.11.6.6 ee)
Rated range of delivered oxygen concentration	201.15.102 a) 1)
Separate *instructions for use* for *lay operator*	201.7.9.2.1.101 a) 1)
Separate *instructions for use* for supervising clinician or the *healthcare professional operator*	201.7.9.2.1.101 a) 2)
Statement to the effect that the *ventilator* is to be equipped with O_2 *monitoring equipment* for the measurement of inspiratory oxygen concentration before being put into service, if not so equipped	201.12.4.101 a) 2)
Statement to the effect that the *ventilator* is to be equipped with CO_2 *monitoring equipment* before being put into service, if not so equipped, if applicable	201.12.4.104 c) 1)
Summary description of the *ventilator* algorithm for determining the *tidal volume alarm limit*, if provided	201.12.1.105 d) 3)
Summary description of the *ventilator* algorithm for determining the *airway pressure alarm limit*, if provided	201.12.4.102 f)

Description of requirement	Subclause
Summary description of the *ventilator* algorithm for determining the expired volume *alarm limit*, if provided	201.12.4.103 g)
Warning statement to the effect that the ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser, if applicable	201.7.9.2.2.101 j)
Warning statement to the effect that to prevent death or serious injury, monitor the patient and the ventilator regularly in order to determine the need to provide emergency ventilation when an alarm sounds or the ventilator malfunctions	201.7.9.2.2.101 a)
Warning statement to the effect that to reduce the likelihood of disconnection and to prevent adverse ventilator performance, use only accessories compatible with the ventilator. Compatibility is determined by reviewing the instructions for use of either the ventilator or the accessories	201.7.9.2.2.101 i)
Warning statement to the effect that unintentional leaks cause indicated volume and expired CO_2 values to differ from actual patient values, if applicable	201.7.9.2.2.101 k)
Warning statement to the effect that when using nebulisation or humidification, the breathing system filter will require more frequent replacement to prevent increased resistance or blockage, if applicable	201.7.9.2.2.101 e)
Warning statement to the effect that when using the ventilator in a carrying case, only use a carrying case that is listed in the instruction for use to prevent adverse ventilator performance which can consequently result in patient death	201.7.9.2.2.101 h)
Warning statement to the effect to always have immediate access to an alternative means of ventilation to avoid patient death or serious injury	201.7.9.2.2.101 c)
Warning statement to the effect to not add any attachments or accessories to the ventilator that contravene the instruction for use of the ventilator or accessory as the ventilator might not function correctly	201.7.9.2.2.101 d)
Warning statement to the effect to not connect the ventilator to the battery of a wheelchair battery-powered wheelchair unless the connection is listed in the instructions for use of the ventilator or wheelchair as this can affect the ventilator performance which consequently can result in patient death	201.7.9.2.2.101 g)
Warning statement to the effect to not cover the ventilator or place in a position that affects proper operation, including applicable examples	201.7.9.2.2.101 b)
Warning statement to the effect to not use the ventilator at an altitude above (insert maximum *rated* altitude) or outside a temperature of (insert *rated* temperature range). Using the ventilator outside of this temperature range or above this altitude can affect the ventilator performance which can consequently result in patient death	201.7.9.2.2.101 f)
Which portions of the *gas pathways* through the *ventilator* can become contaminated with body fluids or by microbial material conveyed by the expired gases during both *normal condition* and *single fault condition*	201.7.9.2.12 aa)

201.C.4 *Accompanying documents, technical description*

Additional requirements for information to be included in the *technical description* of a *ventilator* or its parts are found in Table 201.C.104.

Table 201.C.104 — *Technical description*

Description of requirement	Subclause
Alarm system log capacity	208.6.12.3 i) 1)
Description of a method for checking the function of *alarm system* for *alarm conditions* of this document, if not performed automatically at start-up	201.7.9.3.101 a)
Description of what happens to the contents of the log after the *alarm system* has experienced a total loss of power (*supply mains* and *internal electrical power source*) for a finite duration	208.6.12.3 h)
Interdependence of control functions	201.7.9.3.1.101 b)
Listing of which *alarm conditions* are checked automatically	201.7.9.3.101 b)
Means of restricting access	201.107
Measurement uncertainty for each disclosed tolerance	201.5.101.3 c)
Pneumatic diagram of the *ventilator*, including a diagram for *operator*-detachable parts of the *ventilator breathing system* either supplied or recommended in the *instructions for use*	201.7.9.3.1.101 c)
Statement to the effect that the responsible organization needs to ensure the compatibility of the ventilator and all of the parts and accessories intended to be used to connect to the patient prior to use	201.7.9.3.1.101 f)
Summary description of the detection algorithm for the continuing positive-pressure *alarm condition*	201.12.4.110 c)
Summary description of the filtering and smoothing techniques for all measured or computed variables that are displayed or used for control	201.7.9.3.1.101 a)
Summary description of the means by which the continuing pressure *alarm condition* is detected and a summary description of the detection algorithm	201.7.9.3.1.101 e)
Summary description of the means of initiating and terminating the *inflation phase* while the *ventilator* is operating in each of its *ventilator-modes*	201.7.9.3.1.101 d)
Summary of the test method and the details necessary to reproduce the test results used to test each other *inflation-type*	201.12.1.104 e)
What happens to the contents of the *alarm system* log as it reaches capacity	208.6.12.3 i) 2

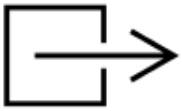
Annex D
(informative)

Symbols on marking

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Annex D applies, except as follows:

Addition:

Table 201.D.2.101 — Additional *symbols* on *marking*

No	*Symbol*	Reference	Title and description
1		ISO 7000-0794 IEC 60878:2015[25]	Input; entrance To identify an entrance, for example exhaust gas entry for measurement (for example of CO-value). For electrical (signal) input use *symbol* IEC 60417-5034.
2		ISO 7000-0795 IEC 60878:2015[25]	Output; exit To identify an exit, for example of a hydraulic pump. For electrical (signal) output use *symbol* IEC 60417-5035.
3		IEC 60878:2015[25] *Symbol* 7.3.1-1 of IEC 62570:2014	MR Safe To identify an item which poses no unacceptable *risks* to the *patient*, medical staff or other persons within the MR environment. When color reproduction is not practical, the *symbol* may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.
4		IEC 60878:2015[25] *Symbol* 7.3.1-2 of IEC 62570:2014	MR Safe Alternative graphical *symbol* representation. Same meaning as IEC 62570-7.3.1-1.
5		IEC 60878:2015[25] *Symbol* 7.3.2 of IEC 62570:2014	MR Conditional To identify an item which poses no unacceptable *risks* within defined conditions to the *patient*, medical staff or other persons within the MR environment. When color reproduction is not practical, the *symbol* may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color. The MR Conditional *symbol* may be supplemented by supplementary *marking* that describes the conditions for which the item has been demonstrated to be MR Conditional.

No	*Symbol*	Reference	Title and description
6		IEC 60878:2015[25] *Symbol* 7.3.3 of IEC 62570:2014	MR Unsafe To identify an item which poses unacceptable *risks* to the *patient,* medical staff or other persons within the MR environment. When color reproduction is not practical, the *symbol* may be printed in black and white. The use of the colored version is strongly encouraged for the added visibility and information provided by the color.

Additional Annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This Annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationales corresponds to the numbering of the clauses and subclauses in this document. The numbering is, therefore, not consecutive.

— **201.1.1 Scope**

There are key contextual differences between a home *ventilator* and a critical care *ventilator*, even for *ventilator-dependent patients*. One difference is the stability of the *patient*. Another is the balance between *ventilation* and other important lifestyle functions, such as eating, speaking, psychosocial aspects, and general physical activity. When choosing and configuring modes, circuits, and *alarm conditions*, the supervising clinician and *patient* need to balance (1) knowledge and certainty of *ventilation* against (2) the *patient's* autonomy and lifestyle.

The definition of a *ventilator-dependent patient* provided in this document correctly identifies that *ventilator-dependent patients* do not necessarily rely on the *ventilator* for every breath. So for many home *patients*, the support offered by a *ventilator* can be intermittent or episodic and even when support is provided, the degree of support can be highly variable. For example, for the chronically tracheotomised *patient*, the act of speech requires a deflated cuff and a variable leak to atmosphere. The cuff often remains deflated throughout the day, and, in the case of volume target *ventilation*, the *tidal volume* is arbitrarily increased to account for the variable lost volume. In this situation, monitoring of both *inspiratory volume* and expiratory volume is likely to be an inaccurate representation of the respired volume. However, it's unlikely that the monitoring of expiratory flow is available anyway, because any benefit of an expiratory limb is outweighed by its encumbrance. The monitoring of end-tidal CO_2 ($etCO_2$) can also be unreliable, particularly if there is any *PEEP* configured (*PEEP* in the presence of leak dilutes the measurement and introduces variability). At night, the cuff can be inflated, requiring the *tidal volume* setting to be altered to avoid over-*ventilation*. An alternate example is intermittent mouthpiece *ventilation*, where the *ventilator* might not routinely sample the expired volume at all.

These very typical situations do not benefit from the expensive instrumentation essential for a traditional *ventilator* to conform with standards. For the tracheotomised *patient*, relative accuracy can be equally effective as absolute accuracy because the volume is adjusted arbitrarily more than half the day. In fact, one 'ideal' strategy can be a robust leak estimation scheme that perfectly compensated for the leak while present, and then decompensated once the leak is resolved. Which is the best home *ventilator*? Is the expense imposed by extra instrumentation justified? The answer is, it depends on the *patient*, the clinical adjustments, the *ventilator*, and the quality of its labelling. Absolute accuracy can be critical. Or it can be that the most robust safety measure is a simple apnoea *alarm condition*, or independent monitoring, or a *patient* prepared to take responsibility in return for autonomy.

Despite this nuanced reality involving a broad range of *patients*, this document draws heavily from the traditional hospital *ventilator* documents. It currently mandates the monitoring of *inspiratory volume*, expiratory volume, or $etCO_2$, and places great emphasis on accuracy of *ventilation* target (pressure or volume) and how this accuracy is maintained in the face of different circuit *accessories*. It mandates the same monitoring accuracy target as the critical care *ventilator* document, across all *VBS* circuit configurations.

Does mandating the traditional *ventilator* requirements serve the ventilated individual well? By doing so, the choice of circuits and *accessories* available to the supervising clinician and *patient* can be unnecessarily constrained. Does loosening the requirements serve the supervising clinician/*patient*/carer any better? It depends on the situation, and so it is a topic better managed by *risk management* than mandatory requirements. For an autonomous dependent *patient*, a life-support *ventilator* with good relative volume accuracy can be entirely appropriate, with judicious configuration of *alarm settings* enabled by well written clinical instructions. The monitoring of expiratory volume and $etCO_2$ is unnecessary. By contrast, an extremely dependent *patient* or one of poor mentation can be routinely reliant on accurate monitoring, possibly independent from the *ventilator*. In short, the monitoring requirements should be commensurate with the fragility of the *patient* and their environment, and the labelling should advise accordingly.

ISO 80601-2-72 *ventilators* are not considered a *physiologic closed-loop control system* due to the fact that parameters monitored during delivery of respiratory gases that are also used to control the delivery of these gases are exclusively physical parameters of the delivered gases. Consequently, these parameters are considered equipment variables as specified in IEC 60601-1-10.

A *pressure-control ventilator* that uses the *breathing system* pressure as a feedback to control *breathing system* pressure is a closed-loop control system, but not a *physiologic closed-loop control system*. The *breathing system* pressure is considered both a 'variable' influenced by the *patient* physical conditions and at the same time a 'feedback variable', but it is not a quantity or condition measured from the *patient's* physiology.

The *patient* by its physical condition is a disturbance on the closed loop system but the *ventilator* does not adjust the *ventilation* therapy settings based on measurement of these *patient* parameters.

The requirements of this document do not require the *ventilator* to adjust *ventilation* delivery parameters based on the detection in the change of physiological conditions of the *patient*. All automatic adjustments of *ventilator* equipment parameters or generated *alarm conditions* are only based on the measurement of physical variables related to the delivery of breathing gas to the *patient-connection port*. In this sense the *ventilator* ends at the *patient-connection port*, (i.e. has no direct contact to the physiological parameters of the *patient*) and a change in the *patient's* physiological conditions is a disturbance to the *ventilator's* control system that does not act to control the physiological change but continues to control the physical variable(s) to their original objectives.

Ventilators create *alarm conditions* when detecting faults in the delivery of breathing gases to the *patient-connection port* but do not adjust therapy setting of the *ventilator*.

The following are examples of medical devices that are considered *physiologic closed-loop control system*.

— An insulin infusion pump that adjusts the rate of insulin infusion to the *patient* based on the measurement of blood glucose. The physiological feedback mechanism is a blood glucose level monitored by the device.

— An external pacemaker that adjusts the pace rate based on the measurement of the cardiac output value. The physiological feedback mechanism is the value detected by the cardiac output monitor.

Unlike a *ventilator*, these devices titrate delivery to the *patient* based on the measured physiological parameter. A *ventilator* will not titrate but will either stop *ventilation* or generate an *alarm condition*.

— **201.3.273 *Professional healthcare facility***

Unlike the *home healthcare environment*, the environment in a *professional healthcare facility* is considered to be a controlled environment. That is, *supply mains* is reliable with minimum variations and sometimes with backup power. The protective earth connection is robust. Temperature, humidity and altitude conditions are stable, and disruptions from electromagnetic disturbances are controlled.

— **201.3.286 *System recovery***

The concept of recovery is mentioned in IEC 62304:2006+AMD1:2015, 5.5.4 d).

— **201.4.3.101 Additional requirements for *essential performance***

Essential performance as "*ventilation* within the *alarm limits* set by the *operator* or generation of an *alarm condition*" is inclusive of those breaths that the *patient* modifies outside of the ventilatory parameters set by the *operator*, but still within the *alarm limits* that are considered safe by the *operator*. It is expected that the *operator* sets appropriate *alarm limits,* which thereby define the *essential performance* for a particular *patient*.

For example, the modern life-supporting *ventilator* has differing modes of *ventilation* that can consist of multiple *inflation-types*. This is necessary as *patient* response to *ventilation* is unpredictable. *Patient*-initiated breaths or breaths where the inspiration is terminated by the *patient* can have characteristics that are different from those that have been set by the *operator*.

— **201.4.3.102 *System recovery***

IEC 62304:2006+A1:2015, 5.5.4 d), identifies fault handling as potentially including recovery. In previous documents applicable to *ventilators*, the management of *risk* associated with *single fault conditions* is limited to specifying that a *single fault condition* not cause the simultaneous failure of both a *ventilation*-control function, and the corresponding *protection device*. It is commonplace that a *ventilator* experiencing *single fault condition* shuts down while providing *alarm signals*. While this is appropriate for some fault modes, for example when a critical hardware component has failed, there are other fault modes where it can be possible for a *system recovery process* to allow *ventilation* to continue.

Many *ventilators* use one or more microprocessors to control *ventilation* and to provide monitoring and *alarm system* functions. Software controlled equipment is inherently susceptible to *single fault conditions* that can be transient in nature. For example, a processing element might stop responding correctly as a result of a software defect, such as a buffer over-run or domain error; memory corruption such as can occur due to ionising radiation; or in input error such as from electromagnetic interference on a *functional connection*.

The *risk* of *harm* to the *patient* is reduced if, in addition to the *ventilator* providing *alarm signals* to indicate the loss of *ventilation* due to *single fault condition*, it can reset and resume *ventilation*. This

might be implemented by having a watchdog processor that can detect the failure of a *ventilation*-control software process and restart the *ventilation*-control processor into a known state.

In some cases, this *procedure* can also be applicable to *single-fault conditions* that result in non-functional hardware components. An example would be a blower motor that stalls as a result of mechanical shock during operation. If the *ventilator* control system is able to restart the blower, and hence resume *ventilation*, this reduces the *risk* of *harm* to the *patient* further below that level that would pertain if the *ventilator* were to remain inoperable, albeit with *alarm signals* active.

The *manufacturer* determines the appropriate system response to a *system recovery process* that fails to restore full functioning. This could occur either because the *single fault condition* is permanent in nature, or because of an ongoing but essentially temporary phenomenon such as continued electromagnetic interference. It is confusing to the *operator* for the system to continually repeat a *system recovery process* that has failed. In this instance it can be more appropriate to enter a *fail-safe state* with an informative *alarm signal*.

— **201.4.6 *ME equipment* or *ME system* parts that contact the *patient***

Since much of the *VBS* is likely to be draped over or around the *patient*, it is likely to come into direct contact with the *patient* during *normal use*. Additionally, the *gas pathways* conduct fluids into or out of the *patient*. As such, the *gas pathways* of the *VBS* and the *ventilator* need to be investigated regarding *biocompatibility* and compatibility with substances that might pass into the *patient* via the *gas pathways*. Also of concern are electrical *hazards* should any circuitry be incorporated into the *VBS*. By ensuring that those items are subject to the requirements for *applied parts*, these issues are addressed by the requirements already in the general standard.

— **201.4.10.2 *Supply mains* for *ME equipment* and *ME systems***

For d.c. *supply mains*, the requirements support operation from lead-acid batteries and automobiles. A typical 12 V lead-acid battery has an open circuit voltage of approximately 12,65 V when fully charged. This voltage drops to approximately 12,06 V when 25 % charged. Furthermore, while cranking the engine, automotive lead-acid batteries are *rated* for their ampacity while maintaining 7,2 V. *Manufacturers* need to consider whether or not their equipment needs to operate under this condition. While the engine is running, the battery charging system typically maintains the .d.c. voltage between 12,8 V and 14,8 V.[27][29] The values for d.c. operation are also consistent with the European standard medical devices carried in an air ambulance as described in EN 13718-1:2008+A1:2020 [30].

— **201.4.11.101 Additional requirements for pressurized gas input**

A *ventilator* designed to be connected to a pressurized gas supply is required to continue to operate reliably throughout its *rated* range of supply pressures; and these pressures can only be maintained if the *ventilator* in *normal condition* does not attempt to draw more flow from the gas source than the gas source is designed to supply. It is also expected that these *ventilators* should be designed to prevent an unacceptable *risk* under possible *single fault conditions* of the pressurized gas supply.

Pressurized medical gas supplies, including *medical gas pipeline systems* and cylinder pressure regulators conforming to current relevant documents, supply gas-specific terminal *outlets* at a pressure that is within an internationally agreed-upon pressure range of 280 kPa to 600 kPa under *normal condition*. It is expected that *ventilators* should operate to their declared specification at any supply pressure within this range.

In the case of a pressure regulator failure, the gas supply pressure could rise to the pressure regulator's supply pressure, which can be cylinder (tank) pressure. To safeguard against this or

similar eventualities, gas-specific medical gas supply systems are required to be provided with a means to limit their output pressure to not more than 1 000 kPa. All gas-powered *ME equipment* should be designed so as not to present an unacceptable *risk* if its supply pressure rises up to this value. There is a specific requirement that *ventilators* should continue operation with acceptable performance such that *patients* can continue to be ventilated until such time as normal operation can be restored or that alternative arrangements can be made.

Ventilators with maximum *rated* input pressures exceeding 600 kPa are required to fulfil these conditions at up to twice their maximum *rated* input pressure.

Under the *single fault condition* that the supply pressure of any one gas drops below 280 kPa, under steady-state conditions, it is understood that a *ventilator* cannot be expected to continue to operate on this gas. However, it is required that in this case, the *ventilator* should detect the unacceptable low pressure, produce an *alarm signal* and also, in the case of two pressurized gas supplies, automatically switch to use the other gas source (oxygen or air) to drive the *ventilator*. This requirement is stated in 201.13.101.

To ensure that the minimum pressure of 280 kPa can be maintained in practice, *medical gas pipeline systems* supplying compressed medical gases through gas-specific terminal *outlets* are designed so that they can maintain this pressure at the input of gas-powered devices while supplying steady-state flows up to 60 l/min at a single *outlet* connected directly to the pipeline; account is taken of the pressure drop in the pipeline supplying the *outlet* and the pressure drop, at 60 l/min, across the terminal unit and the hose assembly connecting the device to the pipeline.

The *medical gas pipeline system* is also required to be capable of supplying sufficient gas that this flow can be drawn from a predetermined number of adjacent terminal units simultaneously. The actual number will have been determined during the design and installation of the *medical gas pipeline system* by the application of a 'diversity factor'; a factor agreed upon between the supplier and *responsible organization* to be appropriate for each section of the installation according to the designated purpose of each area supplied. Recommended diversity factors are formulated to ensure that the *medical gas pipeline system* is capable of supplying an average flow of 60 l/min to the required proportion of terminal *outlets*. However, if the flow demand from many adjacent *ventilators* exceeds 60 l/min, there is an increased possibility that the *ventilator* input pressure could fall below 280 kPa, mainly because of the increased pressure drop across the terminal unit and input hose assembly (also because of the flow-drop characteristic in the case of pressure regulators supplying a single terminal *outlet*).

In addition to steady-state flows of 60 l/min, the switching of the internal pneumatic system and the operation of a *patient* demand system can result in a *ventilator* requiring transient input flows far in excess of 60 l/min. Because of the compressibility of gas at pipeline pressures and the diameter of piping that is employed in order to minimize the pressure drop, such transient demands can generally be accommodated from the gas contained locally within the pipe work of the *medical gas pipeline system*. There can be temporary pressure drops of the input pressure at the inlet of the *ventilator* to below 280 kPa due to transient flows in excess of 200 l/min (over 3 s) but most of these drops will be within the supply hose assemblies specified by the *manufacturer*. *Manufacturers* need to evaluate their own designs to establish whether any consequent transient pressure drop affects the performance of their *ventilator* when used with recommended supply hose configurations and when connected to alternative gas-specific terminal *outlets* such as those fitted to cylinder pressure regulators conforming to ISO 10524-1.

Ventilators that can draw greater average or transient flows during *intended use* are permitted, but their *accompanying documents* are required to disclose those flows and warn of the need for a different diversity factor.

The average flow of 60 l/min is greater than the test flow used during the commissioning of *medical gas pipeline systems*. In itself, this should be of no concern because the conditions specified for the test do not allow a direct comparison between the two values. The subcommittee agreed to the 60 l/min average flow value, and also the 200 l/min for up to 3 s transient flows, during the preparation of the first edition of the current series of documents for *medical gas pipeline systems* and were aware of the need to satisfy that specification when finalizing the *medical gas pipeline system* test requirements.

Manufacturers should be aware that other medical gas supply system documents permit the fitting of gas-specific terminal *outlets* to supply systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their terminal *outlets*.

— **201.5.101 Additional requirements for general requirements for testing of *ME equipment***

After due consideration, the committees decided that where this document specifies adjoining ranges for variables as the basis for testing and the declaration of performance, the end values of both ranges should be applicable to both ranges. This means that a *manufacturer* is free to use a round-number end value (e.g. 300 ml) in specifications and is not forced to truncate artificially the declared range in order to avoid having to also satisfy the test requirements of the adjacent range. This permits, for example, one *ventilator* to have a declared range *tidal volume* of 300 ml to 1 000 ml and another 100 ml to 300 ml, with each *ventilator* only being required to be tested for the conditions specified for ≥300 ml or ≤300 ml, respectively.

— **201.5.101.2 Gas flow rate and leakage specifications**

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally, one atmosphere (101,3 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas 0 °C is used as standard temperature in physics, either 20 °C or 21,2 °C (70 °F) is often used in engineering. In *ventilation*, the gas in the *lungs* has a temperature identical to body temperature (approximately 37 °C) irrespective of the temperature of the gas delivered by a *ventilator*. The volume of a given amount of gas increases by about 13,5 % from 0 °C to 37 °C or by 5,8 % from 20 °C to 37 °C.

Gas delivery systems supplying pressurized gas to medical equipment, including *ventilators*, follow engineering conventions and specify gas quantities and flow rates at *STPD* conditions. This practice is followed in this document for all requirements concerning gas input.

However, *ventilators* conforming with this document are likely to be inflating the *patient's lungs* relative to a local atmospheric pressure between 70 kPa and 110 kPa. In addition, the gas in the *lungs* is always saturated with water vapour regardless of the humidity of the gas delivered from the *ventilator*. With a standard temperature of 0 °C, 1 l of gas referenced to *STPD* can expand the *lungs* by 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different *ventilators*, it is essential that the information for all *ventilators* is referenced to the same standard conditions. Because it is the volume of gas and not the number of molecules that expands the *lungs*, *BTPS* is the appropriate set of reference conditions to use.

In *ventilators,* a variety of flow transducers are used. Whereas a heated-wire anemometer measures the rate of mass flow of the gas independent of pressure, a pneumotachograph measures the flow of gas at the actual pressure. Therefore, the necessary corrections depend on the type of flow transducer. When a pressure correction is required, this can be adequately estimated.

The necessary corrections also depend on the location of the flow transducer in the *VBS*. The humidity of the gas can be zero when the transducer measures the inspiratory flow inside the *ventilator*. However, when the flow transducer is located at the Y-piece, the relative humidity can be

anything up to 100 %. When an *HME* is used for humidification, the output of the flow-transducer depends on whether it is located distal or proximal to the *HME*. With a blower-based *ventilator* that uses ambient air, the humidity of the drawn-in air can be unknown to the *ventilator*. All these effects together inevitably introduce some errors in the conversion of the measured flow signal to *BTPS* reference conditions. However, these errors are only in the range of several percent. However, it remains the responsibility of the *manufacturer* to *verify* that the accuracy requirements of 201.12.1, 201.12.4.102, and 201.12.4.103 are met.

— **201.5.101.3 *Ventilator* testing errors**

When testing *ventilator* performance, several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flows.

Because of the relative significance of these uncertainties, it is important that *manufacturers* allow for them when declaring parameter accuracy.

Similarly, it is important for a third-party tester to recognize the significance of the uncertainty in their own measurements when testing to this document.

In practice, this means that, for example, if a *manufacturer* determines that a parameter has a tolerance of ±7 % but that the measurement uncertainty is ±3 %, then test results are acceptable if, given the uncertainty band for the measured value, the probability of the measured values being within the limit is at least 50 %. In almost all cases, measurement uncertainty has a symmetrical distribution, and the 50 % likelihood criterion is met if the measured value is within the disclosed limit, in this example, within ±10 % of the setting. If a third-party is testing to this document, they also need to include measurement uncertainty in their testing. The third-party testing organization needs to control measurement uncertainty to the same as that disclosed for a type test, which in this example is ±3 %.

Note that a third-party testing organization obtaining a measured value outside the limit does not necessarily invalidate the claim – the deviation from the limit is required to be compared to the uncertainty of the measurement to establish the probability of the data representing a true deviation from specification.

See IEC Guide 115 for more information regarding measurement uncertainty.

Furthermore, the *manufacturer* is required to disclose the measurement uncertainty for each declared value in order to provide both information to the *responsible organization* and guidance for a third-party tester as to the needed measurement accuracy when testing to this document.

This is a change from previous revisions of this document, which required tolerances to be adjusted by subtracting measurement uncertainty from disclosed tolerance values to determine acceptance criteria.

— **201.7.2.3 Consult *accompanying documents***

The committees agreed that following the *instructions for use* is a mandatory action for the safe operation of a *ventilator*.

— **201.7.4.3 Units of measurement**

Additional information is found in rationale for 201.5.101.2.

— **201.7.9.2.2.101 Additional requirements for warnings and safety notices**

— ***d)***

The *operator* should be aware that only the parts or *accessories* listed in the instruction for use have been *validated* by the *manufacturer*. The use of non-*validated* parts can represent an unacceptable *risk*.

EXAMPLE 1 A power supply unit other than the one recommended by the *manufacturer* might be designed and manufactured with poor quality (bad reliability), might affect the electromagnetic compatibility of the *ventilator*, etc.

EXAMPLE 2 The connection of parts to the *VBS* that are not listed in the instruction for use can increase the inspiratory or expiratory pathway resistance of the *VBS*, can increase the unintentional leakage of the *VBS*, etc. to a level that will affect the *basic safety* and *essential performance*.

— ***e)***

The functionality of *breathing system filters* is affected by a number of aspects of structure, properties, and local environment.

At the most basic, a *BSF* is designed to be a filter that removes particles suspended in gas, i.e. a "dry aerosol". The particles primarily targeted in the *VBS* are bacteria or virus particles (although other particles would be subject to retention). The filtering material ("medium") is composed of a matrix of solid material with open passageways to allow gas flow. The passageways in such gas filters are relatively large compared to the bacteria and virus particles that are to be removed. The spatial arrangement of the solid part of the filter medium versus the open spaces in the medium brings the particles in proximity to the surfaces of the medium, where physical forces (electrostatic attraction and Van der Waals forces) attract and bind the particles within the matrix, removing them from the gas flow.

In the practical situation of anaesthesia or respiratory care therapy, environmental factors related to the *patient* or the therapy can alter the performance of the *BSF* from that which would occur in the simple flow of air with suspended microorganisms though the *BSF*.

One major factor is the presence, phase, and amount of moisture present in the gas flowing through the *BSF*.

When there is low humidity in the gas (gaseous phase moisture), the gaseous water molecules generally pass though the filter medium without effect. If there is a sufficiently high relative humidity, some *BSF*s can adsorb or absorb part of this humidity.

If the moisture exists as a liquid aerosol, the water droplets can also be retained by the filter.

The property of a filter medium that governs the degree to which this interaction with water takes place is its relative affinity for water. A medium that readily attracts water is termed "hydrophilic" and a medium that repels water is termed "hydrophobic". These properties are, in fact, not discrete, but exist on a continuous scale. Nevertheless, in common parlance filters are grouped into being (relatively) hydrophilic or hydrophobic.

Another example of liquid phase water can be termed "bulk water". An example of this is the collected condensate that occurs in the expiratory limb of the *VBS*. Depending on the management of the circuit and the positioning of the *BSF*, this bulk water can actually completely cover and occlude the filter. If a sufficient pressure is applied, the liquid water can be forced though the pores

of the filter medium. This requires relatively low pressure for a hydrophilic filter and relatively high pressure for a hydrophobic filter.

The practical consequences of the latter scenario is that if liquid is forced though a hydrophilic *BSF*, gas flow blockage can be relieved, but any microorganisms removed by the filter can be carried past the filter with the liquid stream. In the case of a hydrophobic filter, the pressure in the *VBS* is usually not sufficient to force liquid though the medium, so the microbial retention is not compromised. Airflow occlusion persists, however, until steps are taken to remove the bulk water.

In addition, there can be a temporal aspect to the properties of relative hydrophilicity or hydrophobicity; whereby prolonged exposure to water alters these properties during the *expected service life* of the *BSF*. A *BSF* is typically labelled with an *expected service life*, in hours or days, that reflects its ability to perform to its labelled specifications in the clinical environment.

It should be obvious that the potential influence of water on performance differs in anaesthesia and respiratory care applications, although many, if not most, *BSF*s are indicated for use in both applications.

Additional effects on *BSF* functionality can be caused by the introduction of substances other than water or gas into the device. Such substances can originate from the *patient* (e.g. sputum, exudates, blood, vomitus) or substances introduced by the *operator* into the *VBS* (e.g. gross amounts of medications intended to be nebulised for administration though the *VBS*).

The effect of such substances can be an increase in flow resistance of varying degree up to complete occlusion at *ventilator* or physiologic pressures. In the case of nebulised medications, the type of nebuliser and its operating parameters are variables that affect the likelihood or magnitude of significantly increased *BSF* flow resistance during a prescribed medication regimen. It should be mentioned that accidental introduction of gross amounts of medication from the nebuliser reservoir during *operator* or *patient* manipulation of the *VBS* has been implicated as a source of acute *BSF* blockage.

The cause of increased flow resistance in a *BSF* can be gross blockage of the medium passages or the effects of surfactant properties of the substances introduced into the *BSF* upon the hydrophobicity of the filter medium. It should be noted that medications indicated for nebulisation can contain surfactant materials that are not identified in the medications' labelling with respect to their presence or their quantity, and these can change without notice for a given medication. The effect of these substances upon flow resistance differs among individual models and brands of *BSF*s.

The *operator* needs to be aware that the effects of such substances can be manifested as increases in the amount of positive *airway pressure* required for a *ventilator*-provided breath, or as an increase in expiratory flow resistance, resulting in a step-wise increase in intrapulmonary pressure that, if not detected, can lead to pneumothorax.

Awareness of the possibility, albeit infrequent or rare, of such significant increases in *BSF* flow resistance and inclusion in a trouble-shooting scheme for this and other causes of impaired *ventilation* can reduce or eliminate adverse events occurring secondary to *BSF* flow occlusion.

Direct *patient* monitoring and usage of the appropriate settings for, and prompt attention to, *ventilator alarm conditions* are essential to provide maximum *patient* safety.

Once a *BSF* is recognized to be a source of impaired *ventilation*, simply removing the occluded *BSF* and replacing it with another *BSF* returns *ventilation* to a normal state.

— ***g)***

Wheelchair batteries, even though they mostly convey the appearance that they supply standard voltages for auxiliary battery-powered equipment, often provide neither the appropriate *connector* nor an adequate voltage range to safely supply the *ventilator* for normal operation. Depending on the battery load condition required for the movement of the wheelchair, the voltages supplied at the auxiliary *connector* often show major voltage drops and simultaneous current limitations. It is reasonably foreseeable that these variations are often outside the external *supply mains* ratings of the *ventilator*. These might adversely affect the performance of the *ventilator* or, in the extreme, these voltage fluctuations might lead to a stoppage of *ventilation*. In addition, these *supply mains* variations can also affect the electromagnetic compatibility of the *ventilator*.

The *operator* needs to be aware that only wheelchairs listed in the instruction for use have been *validated* by the *manufacturer*. The use of non-*validated* wheelchairs can represent an unacceptable *risk* for the *patient*.

— **201.7.9.2.8.101 Additional requirements for start-up *procedure***

In some designs, adequate checking of the *alarm system* can be performed with a combination of *operator* action and the power-on self-test routines that *verify* the integrity of the software and the integrity of the computer controlling the *ventilator*, as well as the measuring sensors and the *alarm signal* generation.

— **201.7.9.2.9.101 Additional requirements for operating instructions**

Some *ventilators* are designed so that they can operate with higher-than-normal tubing circuit compliance and resistance. Thus, knowledge of these *VBS* characteristics is important for the *operator* to be aware of the *ventilator* capability. Also, knowledge of the maximum *VBS* resistance (at *nominal* and maximum flowrates) is important because an occlusion *false positive alarm condition* can be caused by the use of high resistance components in the *VBS*. These characteristics of the *VBS* need to be inclusive of any inhalation and exhalation particle/bacteria filters, *humidifier*, nebuliser, water collection vessels, and *connectors* needed for operation.

— **201.7.9.2.9.101.1 *Lay operator* operating instructions**

— ***d)***

This document requires that *instructions for use* for both the *lay operator* and the supervising clinician or *healthcare professional operator* describe methods of testing *ventilator alarm conditions*. It is useless to require these tests unless the tests serve the intended purpose of ensuring that *operators* are alerted to potentially *hazardous situations* while ventilating in the environment of use.

Alarm condition testing instructions for the *lay operator* need to provide simple tasks that create *alarm limit* violations without changing any *ventilator* settings.

Lay operators have a need to know that the *alarm limits* are likely to be violated when common but potentially harmful situations occur. Since *lay operators* might not be allowed to change *ventilator* settings, it is vitally important that they learn how to test a *ventilator* while it is set up with prescribed settings to determine that *alarm limits* are violated during interruption of *ventilation* (due to disconnection, occlusion, etc.) and other potentially *hazardous situations*.

Alarm condition testing instructions for *lay operators* are similar to reverse troubleshooting. A series of simple tasks simulate problems and the *operator* verifies that the *alarm limits* intended to

alert for each problem are violated. It is best if these simulations can be performed without a test lung. For improved *lay operator* confidence, the supervising clinician or *healthcare professional operator* might find it beneficial to demonstrate these tests for the *lay operator*.

For this type of *ventilator*, *alarm condition* testing instructions for *healthcare professional operators* should be as simple as possible, since it is intended that these *ventilators* are used outside of a hospital setting. These tests can require that the *operator* make settings changes and use a test lung in order to test whether the *ventilator alarm systems* are fully functional.

— **201.7.9.2.9.101.2 Supervising clinician operating instructions**

— ***a) 6)***

See rationale for 201.7.9.2.9.101.1 d).

— **201.7.9.2.14.101 Additional requirements for *accessories*, supplementary equipment, used material**

The use of antistatic or electrically conductive materials in the *VBS* is not considered as contributing to any higher degree of safety. On the contrary, the use of such material increases the *risk* of electrical shock to the *patient*.

— **201.7.9.3.1.101 Additional general requirements**

The *manufacturer* is expected to express the description of the *ventilator* in general terms so the reader can understand the important behaviour of the *ventilator* (e.g. mean values and their time specifications, number of *inflations*, and delays etc.). Some items (e.g. pressures) that one would find in the *instructions for use* of a professional use *ventilator* are placed in the *technical description* for this home use *ventilator* as that information is not expected to be meaningful to the *lay operator*, but is necessary for the supervising clinician or the *healthcare professional operator*.

— **201.11.1.2.2 *Applied parts* not intended to supply heat to a *patient***

The objective of this requirement is to protect the *patient* from skin burns due to contact with the external surface of the *breathing tube*.

The human airway has a very significant ability to absorb or deliver heat and moisture. Reference the common practice of sitting in a sauna without *harm* to the respiratory tract.[46] Fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract.[37] A more recent study reported tolerance of inspired gas temperatures of 46,9 °C to 49,3 °C, 100 % RH (265,6 kJ/kg) for 45 min[41].

Taking into account the enthalpy of inspired gas that has been shown to be tolerated without causing thermal injury to the human airways and the very short exposure times of thermal overshoot from a heated *humidifier* in clinical practice, the delivered gas energy limit of 197 kJ/kg of dry gas when averaged over 120 s can be used.

When considering gas mixtures other than oxygen/air, the following should be observed. Given that most of the energy is contained in the water vapour, the equivalent of air at 43 °C, 100 % RH is the maximum enthalpy that should be allowed. This has a specific volume of 0,9786 m^3/kg of dry air and an enthalpy content of 197 kJ/kg of dry air. Assuming the volume breathed by the *patient* is the same whatever gas mixture is used, then the safe enthalpy limit is 197 kJ/kg of dry gas. This enthalpy per unit volume gives a more relevant measure of the energy delivered to the *patient*.

Studies to measure the relative importance of exposure time and temperature in causing cutaneous burns determined that surface temperatures of at least 44 °C and 6 h exposure were required to cause irreversible damage to epidermal cells.[53] This is confirmed by studies conducted by the U.S. Navy Medical Research and Development Command[37] which concluded that fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract.

Gas at body temperature and fully saturated (37 °C and 100 % RH) does not transfer thermal energy to or from the *patient* with a normal body temperature of 37 °C. Dry gas at body temperature (37 °C and 0 % RH) draws heat away through evaporation. Gas at 41 °C and fully saturated has the capacity to deliver less than 130 kJ/kg of dry gas breathed by the *patient*.

— **201.11.6.6 *Cleaning* and *disinfection* of *ME equipment* or *ME system***

The *essential principles* of ISO 16142-1 require that medical devices are not to be operated or used if their condition could compromise the health and safety of the *patient* on whom they are being used or the employees or third parties interacting with them.

This means that *ventilators*, their *accessories,* and parts cannot be used if there is a potential *risk* of the *patient*, *operator,* or other person being infected as a result of contact with the *ventilator*, *accessory,* or part.

Therefore, *ventilators*, their *accessories,* and parts require an appropriate level of *disinfection* depending on their use, but rarely need to be *sterile*.

Recommendations for hygienic *processing* of *ventilators*, their *accessories,* and parts are based on the general hygiene requirements for the *processing* of medical devices and need to take into consideration the special requirements and needs of *patient* care in the clinical environment.[16] The requirements for hygienic *processing* of this document are intended to

— make the *responsible organization* for *processing* the *ventilator* aware of how to implement these tasks in a responsible manner through appropriate delegation, and

— help all parties involved in the *processing* of *ventilators*, their *accessories,* and parts to conform with the *manufacturer's* instructions.

The *cleaning* and *disinfection procedures* of the *manufacturer* are also intended to provide practical support to all those involved in *patient* care in the clinical environment with regards to implementing the hygiene measures required for the *patient's* safety.

It should be noted that *ventilators*, as all other medical devices that have been contaminated with human pathogenic microorganisms, are a potential source of infection for humans. Any *ventilator* that has already been used on another *patient* is potentially contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and *processing procedures* are essential to protect the next person handling the device or the next *patient* on whom the device is used. Hence, *ventilators*, their re-usable *accessories* and parts that have been used are required to undergo a *processing procedure*, following the *manufacturer's* instructions, prior to reuse by another *patient*.

The following basic considerations need to be addressed by the *manufacturer* when specifying the *processing* instructions of a *ventilator*, its *accessories* or parts:

— protecting the *patient*, the *operator,* and the *responsible organization* (including personnel involved in performing the *processing procedure*);

— the limits of the *procedures* used for *processing* (such as the number of *processing* cycles);

— the necessity to guarantee the proven standardised *procedures* to a consistently high and verifiable quality, based on an established quality management system.

The recommended *processing procedure* should be determined by the following:

— the potential degree and type of contamination of the *ventilator*, *accessories* or parts;

— the *risk* of infecting another *patient* resulting from their reuse and the type of application of the *ventilator*.

Special consideration of the possible *risk* associated with the contamination of gas-conducting components due to the *patient's* re-breathing under *single fault condition* should be considered.

On the basis of the above, a *verified* and *validated* documented *processing procedure* needs to be specified in such detail so that the outcome is reproducible. An acceptable *residual risk* from the *hazard* of infection for the next *patient* can be assumed if the following conditions have been fulfilled:

— documented *processing procedure's* effectiveness has been *verified* through appropriate scientific methods by the *manufacturer*;

— reliability of the documented *processing procedures* has been *verified* in practice through appropriate quality assurance measures by the *responsible organization* carrying out the *processing procedures*.

When selecting and evaluating the *processing procedures*, the *manufacturer* should consider the following:

— the amount and type of pathogenic microorganisms expected to contaminate the *ventilator*, *accessories,* or parts;

— the *risk* for the pathogenic microorganisms to be transmitted to the *patient*, *operator,* or other persons;

— the microorganism's resistance to the recommended *processing procedures*.

The *risks* posed by a *processed ventilator*, *accessories,* or parts are determined by the following factors:

a) undesired effects, which can result from the following:

   — previous use;

   — previous *processing procedures*;

   — transportation and storage;

b) the *risks* from subsequent uses, such as the following:

   — residues from the previous use (such as secretions, other body fluids, and drugs);

— residues from the previous *processing procedures* (such as *cleaning* agents, disinfectants and other substances, including their reaction products);

— changes of physical, chemical, or functional properties of the device;

— changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, *connectors* and adhesive joints);

c) the *risk* of transmission of any pathogenic microorganisms.

When considering the suitability of the *processing procedures* and the feasibility of the *processing procedures* for the *ventilator*, *accessories,* or parts, the *manufacturer* should consider the following points:

— *risks* involved in the *processing procedures*;

— cost effectiveness of the *processing procedures*;

— practicability of the *processing procedures*;

— availability of the *cleaning* equipment and the *cleaning* agents specified in the *processing* instructions;

— efficiency of the *processing procedure*;

— reproducibility of the *processing procedure*;

— quality management requirements of the *processing procedure*;

— environmental impact of the *processing procedure* and the disposal of the *ventilator*, *accessories,* or parts.

The *manufacturer* should *verify* all *cleaning* agents and *processing procedures* used with regard to their suitability and repeatability with the *ventilator*, *accessories,* or parts, depending on the type of use.

The *responsible organization* should *verify* that manual *cleaning* and *disinfection* of the *ventilator*, *accessories,* or parts are always carried out in accordance with the *procedures* specified in the *accompanying document*.

The *manufacturer* should specify *validated* automated *cleaning* and *disinfection procedures*. If they are not followed, the effectiveness of the *cleaning* and *disinfection* cannot be guaranteed. Such parameters could include the volume of water used, water pressure, temperature, pH, dosage of *cleaning* agents and disinfectants, and residence time.

To ensure the reproducibility of automated *processing procedures*, tests should be carried out on a regular basis.

The *manufacturer* should ensure that the specified *disinfection procedures* are *verified* to be bactericidal, fungicidal, and virucidal so that the cleaned and disinfected *ventilator*, *accessories,* or parts do not pose an unacceptable *risk* of infection by reproductive pathogenic microorganisms when any of these elements, collectively or individually, comes in contact with the next *patient*, *operator,* or person.

Effective *disinfection* requires that the instructions for the disinfectant, especially with regards to concentration and residence time, are followed.

Following any *processing procedure*, a safety and functional testing of the *ventilator* (as specified by the *manufacturer's* instructions) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before use of the *ventilator*.

The extent and type of the tests depends on the *ventilator*, *accessory,* or part and these need to be defined in the *accompanying document*.

— **201.12 Accuracy of controls and instruments and protection against hazardous outputs**

The committees considered that the accuracy of set and displayed values is a key component of the *essential performance* of a *ventilator* (i.e. the delivery of *ventilation* at the *patient-connection port* within the *alarm limits* set by the *operator* or generation of an *alarm condition*). The general standard requires *manufacturers* to declare accuracies and to address the associated *risks* in the *risk management process*. One of the associated *risks* is lack of consistency between *manufacturers* in their declarations of accuracy, both in terms of the reference settings used and the conditions of test. Consistency in these situations can only be achieved by means of internationally agreed standards and these requirements have been formulated in order to fulfil this objective.

The test settings and conditions and, for certain parameters, minimum requirements, specified in this subclause have been selected by the committees as those necessary to demonstrate adequate *essential performance* of a *ventilator* with regards to the parameters specified. The test *procedures* have been written as *type tests* (additional information is found in 3.135 and Clause 5), with the expectation that *manufacturers* design their own test programmes to ensure that their declared accuracy tolerances for the settings and conditions specified encompass any results obtained by a *type test* performed in accordance with the test *procedures* specified in this subclause.

— **201.12.1.105 *Tidal volume monitoring equipment***

Evidence is accumulating that both volutrauma and barotrauma can result in respiratory morbidity and affect long-term respiratory outcome. Overstretching of the *lung* results in a decrease of the compliance in the respiratory system, an increase in the water content of the *lungs*, and microscopic evidence of alveolar and interstitial oedema, alveolar haemorrhage, and neutrophil infiltration.[51] The immature *lung* is especially vulnerable to injury due to overstretching of the *lungs*.[53] Volutrauma has been characterized by airway modelling and airway hyper-responsiveness in infant rats.[52] In addition, the early onset of airway hyper-responsiveness is a predictor of bronchopulmonary dysplasia in human infants,[53] a condition resulting in permanent *lung* injury.[55] As a result, the *operator* needs to know both the *tidal volume* and *airway pressure* to be able to assess the adequacy of the *patient's ventilation*.

As with the measurement of *airway pressure*, the site of the volume measurement is not specified, but the value is required to be referenced to the *patient-connection port* (additional information is also found in the rationale for 201.12.4.102). The permissible errors in both setting and measurement of *airway pressure* and *tidal volume* are reasonable for *patients* that require more than 50 ml *tidal volume*, i.e. there is little *risk* of over-ventilating or under-ventilating such *patients*. This is less true for smaller *patients*, particularly those requiring *tidal volumes* of less than 50 ml, with stiff *lungs* in *volume-control* modes. As a result, *manufacturers* of *ventilators* intended to deliver *tidal volumes* of less than 50 ml should recommend the initial use of a *pressure-control ventilation-mode* until such time as the cardiorespiratory status of the *patient* has stabilized. Whether *volume-control ventilation* or *pressure-control ventilation* is chosen is less the issue than is the maintenance of non-injurious *tidal volumes* as a function of body weight (usually predicted

body weight or ideal body weight). Although slightly lower than the range for paediatric and adult *patients,* the clinically accepted value for infants lies in the range of 4 ml/kg to 6 ml/kg.

With a non-leaking airway interface such as a cuffed tracheostomy tube, the monitoring of expired volume is preferred as this provides a more accurate estimate of the pulmonary *tidal volume*. It is confusing to the *operator* to have multiple *alarm conditions* based on both *tidal volume* and expired volume, and it is therefore appropriate that the monitoring of *tidal volume* and its associated *alarm conditions* be capable of being disabled when the monitoring of expired volume is in use.

Airway interfaces that allow considerable gas leak are in common use. These include tracheostomy tubes used without, or with an under-inflated, cuff; tracheostomy tubes that incorporate a speech valve (such as Passy-Muir valve); and non-invasive *masks*. In these use situations, the monitoring of expired volume is impracticable and the committees believe that it is imperative that the *tidal volume* monitor remain in use for maintaining *patient* safety when the monitoring of expired volume is not in use.

— ***d) 2) ii)***

In this document the phrase '*responsible organization*-configurable' is used to describe *ventilator* settings that are prearranged either to a specific value or a range of values by the *responsible organization* for a particular setting. *Responsible organization*-configurable settings are normally protected from change by the normal clinical *operator*. When the *responsible organization*-configurable parameter is constrained to a range, the *operator* typically can then adjust the parameter value within the constrained range.

— **201.12.1.106 Response of the *ventilator* to an increase in set oxygen (O_2) concentration**

It is important that changes in the delivered oxygen concentration can be made without major delay. This is especially relevant in cases where a rapid increase of the inspired oxygen concentration is necessary for *patient* care. For instance, it is common practice to preload the *patient* with high concentrations of oxygen for a brief period prior to open suctioning. Depending on the design of the *ventilator* and depending on the settings, significant delays can occur.

The committees could not develop a maximum delay as there are too many possible clinical scenarios. However, the *healthcare professional operator* needs to know how a *ventilator* will respond, particularly to a request for a sudden increase in oxygen concentration delivery.

As a result, a test method has been developed. The results of this test are required to be disclosed in the *instructions for use* so that an *healthcare professional operator* can effectively care for the *patient*.

— **201.12.4.102 Measurement of *airway pressure***

Additional information is also found in the rationale for 201.12.1.103.

The site in the *VBS* at which pressure is sensed varies from *ventilator* to *ventilator*. Generally, the *manufacturer* chooses one of the following two strategies:

— measuring the *airway pressure* by direct sampling at the *patient-connection port*;

— indirectly estimating the pressure at the *patient-connection port* by measuring the pressures at two locations in the *ventilator*: on the inspiratory side of the *VBS* (at the “to *patient*” port) and on the expiratory side of the *VBS* (at the “from *patient*” port), and, after mathematical manipulation, averaging the two values.

— ***e) 2)***

See rationale for 201.12.1.106.

— **201.12.4.103 Measurement of expired volume and low-volume *alarm conditions***

It is desirable to have a fast-responding measurement of volume and narrow *alarm limits*. However, as there is often considerable variation in a *patient's* ventilatory pressures and volumes, narrow *alarm limits* inevitably lead to clinically insignificant *alarm conditions*. As a result, *operators* choose to set wide *alarm limits* to reduce the number of insignificant *alarm conditions* despite the fact that this can compromise *patient* care when there is a prolonged small change in *ventilation*. Therefore, it is recommended that a *ventilator* be designed to use initially a lower priority *alarm condition*, which escalates to a higher priority if the *alarm limit* violation persists. The initial *alarm condition* priority and the priorities and timing of the escalation should be determined by the severity of the potential *harm* to the *patient* in combination with the length of time that the *operator* has to prevent the *harm* from occurring.

When the tracheostomy tube cuff is deflated during *artificial ventilation* exhaled volume monitoring is unreliable at best and likely impossible, especially when a speaking valve [1] is used in conjunction with the deflated cuff. In spite of the impact on exhaled volume monitoring and the associated *alarm conditions*, there are several reasons why it can be preferable to deflate the tracheostomy tube cuff in stable, mechanically ventilated *patients*. These quality-of-life reasons to deflate a tracheostomy tube cuff of a ventilated *patient* are outlined below.

Speech: When the tracheostomy tube cuff is deflated, it allows the *patient* to exhale through the vocal cords and communicate through speech. This is particularly important for children. Introducing the speaking valve as soon as possible after tracheotomy offers more normal speech/language development as the child is able to vocalize (e.g. cry, laugh, coo, and babble), which is an important precursor to speech and is important to the parent/child bonding *process*.

Swallowing food and liquids (including secretions): Deflating the cuff allows the larynx to elevate and move with anterior, natural mechanical motion each time one swallows that keeps the airway safe from food and drink. The larynx is an organ of swallow and closed position speaking valves restore positive subglottic pressure generated during the swallow. That positive pressure happens as the *lungs* recoil during the apnoeic phase of the swallow against closed cords. The pressure builds as high as 10 cmH_2O, and is responsible for preventing food or drink from entering the trachea, and simulating vocal cord closure. When the larynx pulls forward during the swallow, it pulls open the oesophagus; as the oesophagus opens, pressure falls (Boyle's law) and a vacuum environment is created to pull food or drink into the oesophagus, not through cords that have positive pressure under them.

Sensation/protection from aspiration: Redirecting exhaled air through the oropharynx restores sensation and allows the *patient* to feel the back of his throat. If a cuff is inflated, sensation is dulled and the *patient* is at a higher *risk* of aspiration because the cuff is inflated. Oral secretions do not pool in the back of the throat because sensation is restored and the *patient* coughs, clears, or swallows those secretions away.

Cough/airway clearance: *Patients* who are able to close the glottis and build subglottic pressure can have natural cough strength restored and thereby need less invasive suction *procedures*.

[1] An example speaking valve is commercially available from Passy-Muir, Inc., http://www.passy-muir.com/. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO or IEC of this product.

Smell and taste: Tracheotomised *patients* usually lose the ability to smell and taste due to a lack of airflow through the nasal and oral cavities. Use of a speaking valve re-establishes this airflow during exhalation and as a result, olfaction is stimulated.[50] Restoration of olfaction can also facilitate the sense of taste. In turn, *patients* can experience improvement in appetite, which can lead to increased oral intake and improved nutritional status.

Toileting: A closed glottis makes a Valsalva manoeuvre possible. This manoeuvre is used for toileting, upper body strength (e.g. grunting to push yourself out of a chair or lift a heavy object) and to help balance for safer ambulation.

Overall quality of life: A tracheostomy can raise many psychological/quality of life issues for *patients*. Difficulty with communication, as well as secretion management and swallowing problems, can discourage *patients* from attempting to socialize or interact with others. When using a speaking valve, *patients* can breathe, speak, and use their hands more normally without drawing attention to the tracheostomy. *Patients* can use an ascot or scarf to cover the tracheostomy tube from sight if they wish to do so. Restoration of normal speech, reduced suctioning requirements, and improved swallowing facilitate return to a more normal lifestyle. *Patients* can function without feeling disabled and conspicuous because of their tracheostomy. Increased communicative ability can enable *patients* to regain control over their environment and facilitate an improvement in self-esteem and well-being.

Alternative monitoring and *alarm conditions*: For all of the above quality of life reasons, it can be preferable to deflate the tracheostomy tube cuff in stable, mechanically ventilated *patients.* In such cases, it is important to provide alternative monitoring and associated *alarm conditions* that can aid in detecting significant increases in leak or circuit disconnect and then alert the caregiver to those situations. None of these methods can provide direct replacement of exhaled volume monitoring and the associated *alarm conditions* but this document permits the monitoring of expiratory end-tidal CO_2 *(201.12.1.104)* or the detection of high leakage (201.12.4.111).

— ***g) 2)***

See rationale for 201.12.1.106.

— **201.12.4.104 Expiratory end-tidal CO_2 *monitoring equipment***

The monitoring of expiratory end-tidal CO_2 is employed clinically as a surrogate for arterial CO_2 tension. It therefore provides an alternative to monitoring expired *tidal volume* in assessing the adequacy of *ventilation* of the *lungs*. However, in the event of an occlusion or leak within the *VBS*, minute *ventilation* can be significantly reduced, while arterial CO_2 rises. This can result in end-tidal CO_2 monitored values that remain within the clinically acceptable range as the *patient tidal volume* is reduced below the level of physiologic dead space. The committees did not believe that safety could be ensured through use of monitoring of end-tidal CO_2 unless either monitoring *tidal volume* or expired volume was also in use.

It is not intended that this constrain a *manufacturer* to integrate the CO_2 *monitoring equipment* into the *ventilator*. However, when it is not integrated, a *functional connection* between the CO_2 *monitoring equipment* and the *ventilator* is required in order to ensure that the CO_2 *monitoring equipment* is in use. For the purpose of the *type test*, the *manufacturer* is expected to demonstrate that there is a *functional connection* between the *ventilator* and end-tidal CO_2 *monitoring equipment*, such that the resulting *ME system* complies with the requirements of this document. This allows for cases such as when the end-tidal CO_2 *monitoring equipment* is integrated within a vital signs monitor from a separate *manufacturer*.

— **201.12.4.105** ***Maximum limited pressure protection device***

The value chosen for the *maximum limited pressure*[35][42] is a compromise between the need to avoid barotrauma and the need to provide an adequate range of pressure to meet the desire of *operators* specifically to supply high insufflation pressures for paediatric *patients*. 90 hPa is required to permit a *patient* to perform breathe stacking thereby avoiding the need for frequent suctioning.

— **201.12.4.107 Obstruction *alarm condition***

Sustained elevated *airway pressure* levels can cause hazardous increases in intra-thoracic pressure. Such pressure increases can result in decreased venous return, reduced cardiac output, and a subsequent drop in arterial blood pressure. Obstruction of the expiratory limb is the most common obstruction in a *ventilator*. The obstruction of expiratory limb *alarm condition* should be designed to detect promptly a reduced expiratory flow due to an increased resistance in the expiratory limb.

The nature or duration of an occlusion in the expiratory limb of the *VBS* cannot be predicted. Assuming that the occlusion is severe and the safety valve opens quickly, the *patient* is not exposed to potentially injurious high pressures, although at the likely expense of the loss of *PEEP*. Further inspirations, whether or not assisted by the *ventilator*, necessitate *rebreathing* the previously exhaled gas trapped in the inspiratory limb. Given these considerations and their consequences, the associated *alarm condition* is required to be at least *medium priority*. Even if the *ventilator* is highly sophisticated, the presence of an occlusion in the expiratory limb of the *VBS* can compromise the *ventilator's* ability to provide essential respiratory support to the *patient*, which requires prompt action by the *operator*.

Causes of continuing *airway pressure* include a malfunctioning expiratory valve, kinked tubing, and expiratory filter blockage. Nebulised drugs can block expiratory filters within a short time.

Other consequences of incomplete expiration (increased peak *airway pressure* or decreased *ventilation*) can be detected and indicated by other *alarm conditions* required by this document. Practice shows that clinically used *alarm limits* are not always sensitive enough to provide early and specific detection of this potentially *hazardous situation*.

— **201.12.4.108 Partial-occlusion *alarm condition***

Total obstruction of the expiratory *gas pathway* that immediately leads to an increased end-expiratory pressure is detected and acted on as indicated in 201.12.4.107. In this circumstance, the opening of an inspiratory safety valve is also required. More commonly, the underlying causes responsible for total obstruction can also cause a partial obstruction (e.g. minor kinking of the expiratory hose) or a slowly increasing resistance (e.g. due to slow build-up of nebulised aerosols on an expiratory *breathing system filter*, dependent on the filter material and the composition of the nebulised drug).

Partial obstruction not only leads to *patient* discomfort (increased expiratory work of breathing, missing triggers), but can develop into total obstruction. It is therefore desirable to detect and alert the *operator* to increased resistance of the expiratory limb as early as possible to give the *operator* sufficient time for remedy without interrupting *ventilation*.

This document does not specify the degree of obstruction that should be detected or the priority of the partial obstruction *alarm condition*. The sensitivity that can be achieved without generating *false positive alarm conditions* not only depends on the design of the *ventilator*, but also on the characteristics of the individual *patient*. Therefore, the committees came to the conclusion that it is not desirable to be more specific.

— **201.12.4.109 Hypoventilation *alarm condition***

Any disconnection is a life-threatening situation for *ventilator-dependent patients*. These situations need to be recognized and remedied as quickly as possible. The hypoventilation *alarm condition* is essential for this purpose. This document requires the *manufacturer* to implement a hypoventilation *alarm condition* that can detect not only hypoventilation caused by changes in the physiological status of the *patient* but also *single fault conditions* such as lack of connections or disconnections in the *breathing system*, to the *airway device* or to the *ventilator ports*.

— **201.12.4.111 High leakage *alarm condition***

The high leakage *technical alarm condition* is permitted to be used as a surrogate for expired volume monitoring and its associated *alarm conditions*. The *manufacturer* needs to ensure that the high leakage *technical alarm condition* is robust and thereby proven to provide a reasonably safe alternative. It is suggested that a combination of flow, time, and pressure monitoring along with pattern recognition be used to determine if high leakage has occurred.

— **201.12.101 Protection against accidental adjustments**

Unacceptable *risks* to the *patient* can occur as a result of accidental adjustments of operating controls or turning off the *ventilator*. To control this *risk*, the *operator interface* should be designed to prevent accidental adjustments. The *usability engineering process* is used to ensure that these *risks* are reduced to acceptable levels. Example methods could include mechanical *risk control* techniques such as locks, shielding, friction loading and detents; pressure-sensitive finger pads; capacitive finger switches; and microprocessor-oriented "soft" *risk controls* or a specific sequence of key or switch operations.

— **201.13.2.101 Additional specific *single fault conditions***

Operation of a *ventilator* without an *operator*-detachable *breathing system filter* in place is considered reasonably foreseeable when considering those parts of the *VBS* that might become contaminated with body fluids or expired gases. If a *ventilator* can operate without the *breathing system filter*, then one should assume that it has been operated without the *breathing system filter* and therefore, those parts of the *VBS* have been contaminated. Additional information is also found in the rationale for 201.11.6.6.

— **201.13.2.103 Failure of *functional connection* to a *ventilator* control or monitoring means**

This requirement prevents the use of a monitoring device to control an actuator that would lead to an undetected malfunction of the actuator in case of monitoring failure.

— **201.13.101 Failure of one gas supply to a *ventilator***

This sub-clause encompasses two distinct use cases.

Many *ventilators* have an oxygen inlet intended for connection to a gas pipeline or cylinder, an inlet or intake for air and provide a control for setting the inspiratory oxygen concentration. This implies that the *intended use* of the *ventilator* includes the provision of oxygen to a set concentration. To control the *risk* in the event of a failure, this document specifies (see 201.12.4.101) that the *ventilator* also include – or be used with – oxygen *monitoring equipment*.

In this class of *ventilator*, when the gas supply at one inlet fails, the *ventilator* is required to automatically switch to maintain *ventilation* using the remaining gas supply, the internal blower or pump, as applicable. A *technical alarm condition* is required to inform the *operator* of the failed gas

supply, as this implies a restriction of the available range of control of inspiratory oxygen concentration, whether or not it results in an immediate change to the inspiratory oxygen concentration.

Ventilators do exist that do not include a control for setting the inspiratory oxygen concentration. Typically, these *ventilators* use a blower to provide air for *ventilation*, and they entrain oxygen from a low-pressure source such as oxygen cylinder with an integrated flow meter or a domiciliary oxygen concentrator. The *intended use* for such *ventilators* cannot include the provision of oxygen to a set concentration. In this case, the *ventilator* is not required to detect, and provide *technical alarm condition* for, failure of the oxygen supply, and neither is it required to include, or be used with, oxygen *monitoring equipment*.

— **201.13.102 Independence of *ventilation* control functions and related *risk control* measures**

This requirement prevents the use of a monitoring device to control an actuator that would lead to an undetected malfunction of the actuator in case of monitoring failure.

— **201.13.103 Failure of *functional connection* to a *ventilator* control or monitoring means**

Independent how the *functional connection* between the "ventilator module" and the remote control or monitoring module is facilitated (e.g,. wired or wireless) this *functional connection* needs to be so designed and constructed that a failure or loss of the *functional connection* does not cause an unacceptable *risk* to the *patient*.

First of all, this means that the safety of the *patient* is not degraded by the loss of the *functional connection*, (i.e., the "ventilator module" continues to ventilate the *patient* without any change of the ventilation parameters, without any change of setting of safety means and without any change of the setting of *alarm limits*). Further, the *healthcare professional operators* in both locations where these modules are located need to be made aware by *alarm signals* about the loss of this *functional connection* (i.e. there is a need for *alarm signals* on both sides of the *functional connection*—at the "ventilation module" and on any other remote control or monitoring module or the *distributed alarm system* or the simple remote *alarm signal* generator).

— **201.16.2 *Accompanying documents* of an *ME system***

Many respiratory gas *humidifiers* control their humidification output by servo controlling the temperature of a water bath to achieve a set gas temperature at the *humidifier* chamber *outlet*. This temperature is frequently defined to be a function of gas flowrate as measured by the *humidifier*, and is defined to target a desirable absolute humidity – the rate of evaporation of water and the rate of heat transfer from the water to the air are closely correlated. This works provided the input gas temperature is below a threshold. For example, for one leading *manufacturer* of *humidifiers*, the water vapour output starts to reduce when the input gas temperature exceeds 27 °C.

A *ventilator* that incorporates a blower to provide a source of breathing air drawn from an air intake inevitably increases the temperature of the air above the intake temperature. The extent of this rise in temperature will depend on the set FiO_2 (and hence the proportion of the breathing gas that has been compressed), the blower *outlet* pressure (which can significantly exceed the *ventilator gas output port* pressure), the *ventilator set rate*, *BAP*, and set *Δ inspiratory pressure* or *tidal volume*, and the efficiency of the blower technology used.

This has been confirmed in published bench study[61]. This study confirmed that with unfavourable conditions, specifically *humidifier* chamber *inlet* gas temperatures above 37 °C, class 1 *humidifier* output could fall below 20 mgH_2O/l.

For a *ventilator* capable of generating an elevated gas temperature at the *gas output port*, the *responsible organization* needs to have information available to allow them to determine whether the *humidifier* is likely to remain effective.

— **201.101.1.2 Filter**

The intention of filtration of the gas from a *high-pressure inlet port* is to protect the sensitive components (e.g. flow sensors) of the *ventilator gas pathways* from particles. This gas is provided from a *medical gas pipeline systems* or from gas cylinders.

The documents for high-pressure oxygen compatibility[13] and pressure regulators[6] require input filtering that prevents particles greater than 100 µm from entering. This filtering minimizes particles as means to control the *risk* of ignition by high velocity particles in a pressurized, oxygen enriched environment. These documents also emphasize the need to proper filter material.

Despite these requirements, in the following cases particles with larger sizes could occur:

— particles collected in *high-pressure inlets* and port *connectors*;

— *high-pressure inlets* of *ventilators* while disconnected; or

— malfunction of *medical gas pipeline systems*, medical air compressors, oxygen concentrators or filters.

Depending on the design of a specific *ventilator* (e.g. in case that particle-sensitive sensors are used) significantly smaller filter sizes than 100 µm can be required.

— **201.101.2.1 General**

Non-standard *VBS connectors* can represent an unacceptable *risk* as attempts are made to fit a standard *VBS* to a *ventilator* in an emergency situation. Non-standard *VBS connectors* can cause leaks if used with similar but not compatible *connectors*.

See also rationale for 201.101.2.2.5.

— **201.101.2.2.3 *Manual ventilation port***

Although provision for the manual *ventilation* of the *patient* in cases of emergency is strongly encouraged, the committees decided that this should be by means of a connection into the detachable part of the *ventilator breathing system* or at the *patient-connection port*. It was decided that the use of a connection port on the *ventilator* could lead to misuse or confusion, with no compensating advantage.

— **201.101.2.2.4 *Flow-direction-sensitive components***

Flow-direction-sensitive components commonly used with a *ventilator breathing system* include flow sensors, non-return valves, *breathing system filters* and *heat and moisture exchangers*.

Use errors associated with these components can include the component being placed ‘in reverse’ (such that the direction of flow is not as intended through it) and can also include the component being placed at an incorrect location within the *ventilator breathing system*.

Each of these use errors can potentially cause *risk* of *patient harm*. In some cases, this is indirect *harm.* For example, a flow sensor placed in the intended location, but incorrect orientation is likely

to result in incorrect output from expired volume *monitoring equipment* and can cause incorrect delivered *tidal volume*. In other cases, the *harm* is direct. For example, a non-return valve placed in an incorrect location can cause a complete cessation of inspiratory or expiratory flow, resulting in complete loss of ventilation.

At least one case has been reported of post-operative ventilation where a non-return valve was used as if it were an adapter to replace an inline nebuliser when it was removed from the circuit. In the reported case, the non-return valve resulted in complete occlusion of the exhalatory pathway, and the *patient* subsequently died.

This standard includes several requirements applicable to *flow-direction-sensitive components*, including *marking* with an arrow for flow direction [201.7.2.101 a) 4)], *instructions for use* [201.7.9.2.14.101 b) 1)], and the constructional requirements of 201.101.2.2.4. However, it is recognised that simply providing a *flow-direction-sensitive component* with mating (rather than identical) *connectors* at *inlet* and *outlet* is not sufficient to prevent all hazardous use errors. *Manufacturers* are expected to consider all foreseeable use errors, including errors of incorrect substitution and incorrect placement as well as incorrect orientation in their *risk management process.*

— **201.101.2.2.5 *Gas pathway* connection port**

The use of Luer taper or Luer-lock *connectors* conforming with ISO 594-1 and ISO 594-2 are permitted for use for connection with the *gas pathways* of a *VBS.* However, this is only permitted when appropriate information for safety is also provided at the *VBS* connection as a *risk control* measure. Nonetheless, there are several case reports of accidental connection with intravenous or other fluids causing serious morbidity and mortality due to aspiration of these foreign substances into the *lungs*.

The committees expect to change this requirement in the next edition or revision to the R1 *connector* of ISO 80369-2 once ISO 80369-2 is published.

— **201.102.1 General**

It is the responsibility of the *manufacturer* of a *ventilator breathing system*, its parts, or *accessories* to *verify* that their product complies with the requirements of this document by testing their product, in combination with the other items for which compatibility is claimed, to the requirements of this document.

— **201.102.4 Water vapour management**

Water management refers to the complete *process* by which moisture, in the form of water vapour, is added to the breathing gas delivered to the *patient's lungs* and the *process* by which humidified breathing gas is conducted back to the *ventilator's* expiratory system and exhausted to the room. Intrinsic to this *process* is the necessity to remove bulk water due to condensation of moisture attributable to pressure and temperature changes in the *VBS*. Even if breathing gas reaches the *patient-connection port* without any added moisture, the expired breathing gas directed back to the *ventilator* contains a finite quantity of moisture. Water management in the *VBS* requires attention, whether or not the *VBS* contains an active *humidifier*, with or without heated wires in the inspiratory or the expiratory limbs of the *VBS*, or a passive or an active *HME* at the *patient-connection port*.

Proper management of the *patient's* airway secretions and mucociliary transport system requires that the *ventilator* compensate for the humidity deficit caused by intubation, which bypasses the upper airways where the normal humidification *process* would begin. Excess moisture delivered to

the *patient-connection port* can flood the cilia located in the bronchial airways, diminishing their ability to move mucus toward the trachea. On the other hand, insufficient humidification of the inspired breathing gas dries the bronchial airways, which leads to thickening of the mucous secretions and likely increased airway resistance or worse. A balanced approach to humidification is needed to maintain healthy cilia. Liquefied mucus can be readily aspirated using a *suction catheter*.

Optimal humidification of the *patient's* airways results from an understanding of the physics of the techniques chosen to add water vapour to the inspiratory gas stream. Depending on the system selected for delivering humidified breathing gas to the *patient* (for example, an active vapour *humidifier* with or without heated wires, conventional *HME* or active *HME*), condensate can accumulate in the inspiratory limb of the *VBS*. If condensation occurs, the *VBS* needs to provide a method by which the liquid can be removed.

In all but the most unusual circumstances, gas leaving the alveoli is saturated at 37 °C. Rainout persists as the moist gas cools and moves toward the *patient-connection port* and is conducted back to the *ventilator*. If an *HME* is fitted at the *patient-connection port*, approximately 50 % to 70 % of the water vapour will be trapped in the *HME*. Whatever the configuration of the expiratory limb of the *VBS*, the water vapour content of the exhaled gas is significant, nearing saturation. Without heated wires, the returning gas cools, causing significant condensation. As in the inspiratory limb, this liquid needs to be removed. The presence of heated wires in the expiratory limb lessens or eliminates condensation before the expired gas enters the *gas return port* of the *ventilator*, but from this point to the *exhaust port*, the gas tends to cool further, so more moisture condenses. The *VBS* needs to include some means to manage this additional condensed water.

— **201.102.6.2 Non-invasive *ventilation***

The inaccuracies are due to the nature of the non-intentional leaks (such as those that occur when a *patient's* mouth opens when on a nasal *mask* or when the *mask* seal begins leaking when the pressure inside reaches a certain level).

— **201.103 Spontaneous breathing during loss of power supply**

A previous version of this document (ISO 10651-2:2004) required disclosure of the resistance under failure conditions. The committees concluded that a *patient* in this state can breathe spontaneously under these conditions until alternative *ventilation* is provided. Previous documents for *ventilators* have required that the pressure drop be less than 6 hPa (6 cmH_2O) at 60 l/min for adults. Spontaneous breathing is only needed to bridge the time until alternative *ventilation* is provided. The committees came to the conclusion that a mere disclosure is not sufficient. The chosen values are regarded as more realistic and sufficient for this infrequent event and were tailored to the intended range of *tidal volumes*.

— **201.104 Indication of duration of operation**

Ventilators require maintenance for continued safe use. A practicable means to ensure that this information is available to the *operator* or the *responsible organization* is to require that the *ventilator* keep track of how long it has been in operation.

— **201.105.2 Connection to electronic health record**

Electronic documentation of *patient* care interventions is rapidly becoming the standard of care. The primary motivations are to improve the quality of care for an individual *patient* through accurate and complete documentation and to improve the completeness and accuracy of aggregate

data to facilitate continuous quality improvement. Providing remote supervisory capability is rapidly becoming the standard of care in the *home healthcare environment*.

— **201.105.3 Connection to *distributed alarm system***

Patients who are *ventilator-dependent* are not always located near enough to the *lay operator* to ensure that *alarm signals* coming from the *patient's* room can be heard. It is reasonably foreseeable that some rooms of a *patient's* home or limited care facility are out of earshot of other rooms. As a result, it is necessary for a *ventilator* intended for use in the *home healthcare environment* to be equipped with a means to connect to a *distributed alarm system* that can provide additional *alarm signal* presentation points. A *distributed alarm system* facilitates delivery of *alarm signals* to other rooms where the *operator* might be located, thereby permitting a timely response and intervention to support *patient* care.

— **202.4.3.1 Compliance criteria**

It is not the intent of the committees to require that the *immunity* tests be performed multiple times (e.g. with *volume-control inflation-type* and *pressure-control inflation-type* at several *tidal volumes*), but that the *manufacturer* should determine which *inflation-type* and *tidal volume* represents the worst-case for a given *immunity* test and use those conditions.

The committees considered whether a pressure error acceptance criterion was necessary. For a given set of test conditions and parameters, the compliance and resistance are fixed. As a result, an error in pressure is reflected as an error in *tidal volume*. Therefore, the committees consider the *tidal volume* acceptance criteria sufficient.

— **206.102 Training**

The modern *ventilator* is complex equipment whose use requires specific training for each *manufacturer's* make and model. Different *manufacturers* often refer to similar modes of *ventilation* by different names and although in principle, those modes are similar to those of another *manufacturer's ventilator*, their modes are unique in sometimes minor and sometimes complex ways. It is essential, therefore, that the *lay operator* and every person involved in the operation and setup of a *ventilator* is fully trained in that *ventilator's* operational characteristics; in particular, its controls, capabilities, and limitations, prior to any use.

— **208.6.8.4.101 Additional requirements for termination of *alarm signal* inactivation**

Permitting very long pauses of *alarm signals* can be hazardous for the *patient* since the *operator* will not be notified of the existence of an *alarm condition*. However, *patient* management often requires *procedures* that can be disrupted by auditory *alarm signals*. Therefore, extending *audio paused* by *operator* action is useful to prevent the *ventilator* from disturbing the *operator* or others in the vicinity.

Ventilators should be equipped with an *audio paused* capability that permits the *operator* to pause the *alarm signals* prior to the creation of an *alarm condition*. Such a capability permits the *operator* to minimize nuisance auditory *alarm signals* in situations that are known to be associated with creation of nuisance *alarm conditions*. A 'planned' disconnect is a common situation where this capability is needed. Examples include open suctioning, *breathing system filter* change, or insertion of a medication treatment. A closed suctioning mode should also include such a capability.

— **211.8.4.101 Additional requirements for interruption of the power supply/*supply mains* to *ME equipment***

Two hours was chosen as the minimum acceptable time necessary to ensure that alternative arrangements could be made to continue the life-supporting function. Climatic, traffic, and other conditions require at least this period before restoration of power or arrangement for other supplies.

Annex BB
(informative)

Data interface requirements

BB.1 Background and purpose

Heightened interest in the monitoring of *ventilators*, as well as accountability and responsiveness of the parties involved, has become evident on an international scale. Consequently, *patients*, caregivers, clinicians, service providers, and payers have begun the systematic definition and collection of information with regard to monitoring the performance of this type of *ventilator*. This trend is also driven by an enhanced data infrastructure. In order to establish a common definition for monitoring the ventilatory performance of the *ventilator*, explicit criteria need be applied to choosing and defining parameters. This framework is intended to inform about a common definition of parameters for *ventilators*. The selection is based on some agreement about what is to be monitored and for what purpose.

It is important to note that any data collection needs to be carried out according to privacy and confidentiality legislation and ethical principles.

A harmonized effort to develop internationally accepted therapy indicators for *ventilators* not only fosters increasingly robust cross-national analyses, but can also facilitate the development of comparable data that can be used as a basis for the setting of international benchmarks.

The standardization of data available from *ventilators* is intended to help to eliminate the current shortcomings and significantly contribute to the improvement of the therapy. This approach seeks to provide a definition that can be used across *ventilator* therapy systems for providing therapy data independent of *ventilator manufacturer* or what mechanisms are used to transport the data, either locally or remotely to a supervising clinician. This approach ensures comparability between data regardless of the transport mechanism chosen to be most appropriate for a *patient* situation. It also provides for flexible and cost-effective integration into disparate systems that supervising clinicians can use for *patient* data management. This approach also maintains comparability between data while allowing advancement in data transport technology to provide solutions that better meet the needs of *patients*, caregivers, clinicians, service providers, and payers. As such, the definition of specific device communication interface hardware or software considerations such as protocols or transport mediums is outside of the scope of this document.

A number of monitoring requirements exist for *ventilators*, depending on the needs of the *patient*, caregiver, clinician, service provider, and payer, which require various levels of data. This document seeks to define the data that for *ventilators* that are required to provide to meet the objectives of these users.

The following levels of data are defined.

— **Parameters and units of measurement:** Parameters and units of measurement used in the *ventilator*

— **Equipment identification:** Information identifying the *ventilator*

— **Usage monitoring:** Temporal data relating to the use of the *ventilator*

— **Equipment settings:** The different therapy modes provided by *ventilators* that require different settings

— ***Ventilation* monitoring:** Settings relating to *patient ventilation*